Supreme Court, U.S.
FILED

No. (1)

93-1450 MAR 11 1994

IN THE

Supreme Court of the United States

OCTOBER TERM, 1993

CEDARS-SINAI MEDICAL CENTER,
WARREN S. GRUNDFEST, M.D., JAMES S. FORRESTER, M.D.,
and FRANK LITVAK, M.D.,

Petitioners,

vs.

SECRETARY OF THE
UNITED STATES DEPARTMENT OF ENERGY,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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138pp

QUESTIONS PRESENTED

The Court of Appeals for the Federal Circuit held that the Secretary of the Department of Energy ("DOE") had made a final Determination pursuant to 42 U.S.C. § 5908, thereby vesting in the government certain patent rights previously owned by the Cedars-Sinai Medical Center ("Cedars"). Applying the two-prong test (*i.e.*, fitness for judicial resolution and hardship) set forth in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967) for judging the justiciability of *pre-enforcement* administrative conduct, the Federal Circuit nevertheless concluded that the District Court lacked subject matter jurisdiction over Cedars' challenge to the DOE's Determination. Specifically, the Federal Circuit held that Cedars failed to prove that the taking of its patent rights imposed sufficient hardship to satisfy the second prong of the *Abbott* test.

The questions presented are:

1) Does the two-pronged *Abbott* test for justiciability of *pre-enforcement* agency actions apply to an agency's *final taking* of property rights? (As to this question, the Courts of Appeals are in conflict.)

2) If the two prongs of the *Abbott* test are applicable, should proof of direct and substantial hardship be required before allowing judicial review of a claim that an agency action wrongfully, and finally, took property rights?

PARTIES TO THE PROCEEDING

Petitioner Cedars-Sinai Medical Center ("Cedars") is a not-for-profit California corporation.[1] Petitioners Warren S. Grundfest, James S. Forrester, and Frank Litvack are cardiac surgeons on the medical staff at Cedars.

Respondent Secretary of the United States Department of Energy is named pursuant to Supreme Court Rule 35.4. The Defendant and Appellee below was James D. Watkins, the former Secretary. The current Secretary is Hazel O'Leary.

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[1] Pursuant to Supreme Court Rule 29.1, Cedars notes that it has two subsidiary corporations, Cedars-Sinai Medical Center Foundation and Cedars-Sinai Care.

TABLE OF CONTENTS

Page

QUESTIONS PRESENTED i

PARTIES TO THE PROCEEDING ii

LIST OF APPENDICES iv

TABLE OF AUTHORITIES vi

REPORTS OF OPINIONS BELOW 1

JURISDICTION 1

STATUTORY AND CONSTITUTIONAL PROVISIONS INVOLVED 1

STATEMENT OF THE CASE 4

1. Summary 4

2. The Holding Below Regarding Proof of Hardship 6

REASONS FOR GRANTING THE WRIT 9

1. The Federal Circuit Misapplied Abbott, in Conflict with the Court of Appeals for the District of Columbia Circuit 9

2. If The Demonstration of Hardship is a Necessary Predicate to Jurisdiction Over Final Agency Actions, A Governmental Taking of Title to Property Inherently Satisfies That Predicate 15

CONCLUSION 23

LIST OF APPENDICES

APPENDIX A
Decision on Appeal, U.S. Court of Appeals for the Federal Circuit, December 13, 1993 . . . A1

APPENDIX B
Order Dismissing Action Without Prejudice, U.S. District Court for the Central District of California, May 19, 1992 . . . . . B1

APPENDIX C
Decision on Preliminary Motions, U.S. Patent and Trademark Office, August 20, 1992 . . . . . C1

APPENDIX D
Reconsideration, U.S. Patent and Trademark Office Before the Board of Patent Appeals and Interferences, February 2, 1993 . . . . . D1

APPENDIX E
Decision on Petition, U.S. Patent and Trademark Office Before the Commissioner of Patents and Trademarks, May 24, 1993 . . . . E1

APPENDIX F
Complaint, U.S. District Court for the Central District of California, January 9, 1992 . . . . . F1

APPENDIX G
Affidavit of Fred A. Cafasso,
December 17, 1991 . . . . . G1

APPENDIX H
Affidavit of Paul M. Yaeger,
March 19, 1992 . . . . . H1

APPENDIX I
Second Affidavit of Paul M. Yaeger,
April 1, 1992 . . . . . I1

APPENDIX J
Affidavit of Coe A. Bloomberg, Esq.,
May 4, 1992 . . . . . J1

APPENDIX K
Motion to Dismiss Complaint,
April 13, 1992 . . . . . K1

APPENDIX L
42 U.S.C. § 5908 . . . . . L1

TABLE OF AUTHORITIES

Page

CASES

Abbott Laboratories v. Gardner,
387 U.S. 136 (1966) 6, 9-13, 15, 17, 19

Ali v. INS,
661 F.Supp. 1234 (D.Mass. 1986) 15

American Petroleum Institute v. U.S. EPA,
906 F.2d 729 (D.C. Cir. 1990) 13

Consolidated Rail Corp. v. United States,
896 F.2d 574 (D.C. Cir. 1990) 12, 13

Continental Can Co. USA, Inc. v. Monsanto Co.,
948 F.2d 1264 (Fed. Cir. 1991) 17

Filmtec Corp. v. Hydranautics,
982 F.2d 1546 (Fed. Cir. 1992) 10

Haitian Refugee Center v. Civiletti,
503 F.Supp. 442 (S.D. Fl. 1980) 13

James v. Campbell,
104 U.S. 356 (1882) 16

Ohio National Life Insurance Company v. United States,
922 F.2d 320 (6th Cir. 1990) 19

Patlex Corp. v. Mossignhoff,
758 F.2d 594, *modified*,
771 F.2d 480 (Fed. Cir. 1985) 16

Williamson v. Tucker,
645 F.2d 404 (5th Cir. 1981) 18

STATUTES

U.S. Constitution, Amendment V 1, 16

5 U.S.C.
§ 702 - § 706 4

28 U.S.C.
§ 1254(1) 1
§ 1295(a)(1) 4
§ 1331 4
§ 1338 4

42 U.S.C.
§ 5908 . . . . . 2, 5, 6, 10, 17

Internal Revenue Code
§ 501(c)(3) 18

Petitioners respectfully pray that a writ of certiorari issue from this Court to review the judgment of the United States Court of Appeals for the Federal Circuit ("Federal Circuit"), entered on December 13, 1993.

REPORTS OF OPINIONS BELOW

The judgment and decision of the Federal Circuit, 11 F.3d 1573, appears unofficially at 29 U.S.P.Q.2d 1188, and is attached as Appendix A. The District Court opinion in this case was not published, and is attached as Appendix B.

JURISDICTION

The judgment of the Federal Circuit was entered on December 13, 1993. This court has jurisdiction to review that judgment under 28 U.S.C. § 1254(1).

STATUTORY AND CONSTITUTIONAL PROVISIONS INVOLVED

United States Constitution, Amendment V:

> No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

42 U.S.C. § 5908(a):[2]

> Whenever any invention is made or conceived in the course of or under any contract of the Secretary, other than nuclear energy research, development, and demonstration pursuant to the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.) and the Secretary determines that ——
>
> > (1) the person who made the invention was employed or assigned to perform research, development, or demonstration work and the invention is related to the work he was employed or assigned to perform, or that it was within the scope of his employment duties, whether or not it was made during working hours, or with a contribution by the Government of the use of Government facilities, equipment, materials, allocated funds, information proprietary to the Government, or services of Government employees during working hours; or
> >
> > (2) the person who made the invention was not employed or assigned to perform research, development, or demonstration work, but the invention is nevertheless related to the contract or to the work or duties

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[2] The full text of 42 U.S.C. § 5908 is set forth in Appendix L.

he was employed or assigned to perform, and was made during working hours, or with a contribution from the Government of the sort referred to in clause (1).

title to such invention shall vest in the United States, and if patents on such invention are issued they shall be issued to the United States, unless in particular circumstances the Secretary waives all or any part of the rights of the United States to such invention in conformity with the provisions of this section.

STATEMENT OF THE CASE

1. Summary

Cedars' action in the District Court against the Secretary of the Department of Energy was brought pursuant to jurisdiction conferred under 5 U.S.C. §§ 702-706 and 28 U.S.C. §§ 1331 and 1338 (App. A13-14; F4). Cedars' appeal from the District Court's judgment was to the Federal Circuit, pursuant to jurisdiction conferred by 28 U.S.C. § 1295(a)(1).

Cedars is a not-for-profit 1,200-bed hospital, located in Los Angeles, California (App. F2-3). Cedars has a medical staff of 2,220 members, among them petitioners Drs. Warren Grundfest, James Forrester, and Frank Litvack (App. F2). In 1983, Dr. Grundfest, a cardiac surgeon, asked permission to use the DOE's laser facility at Argonne National Laboratory ("Argonne") to conduct specific experiments on heart tissue (App. F13 at ¶ 28). He was welcomed at Argonne in order to foster "nominal collegial interchanges" (App. G3). He went there on a Saturday afternoon, so as not to disrupt the normal laboratory activities. Later, Dr. Grundfest and his two fellow surgeons, Drs. Forrester and Litvack sought patent protection for their method of heart surgery called laser angioplasty (App. F4 at ¶ 8). Unbeknownst to these Cedars doctors, DOE personnel present at Cedars' experiments (none of whom were medical doctors, much less heart surgeons) filed their own patent application directed to laser angioplasty based on Cedars' experiments at Argonne (App. F5 at ¶ 10).

When Cedars learned of the DOE's patent filing, Cedars sought to have the true identity of the inventors of the laser surgery method determined by a patent interference

proceeding. The Patent Office granted Cedars' request and declared the interference proceeding (App. F5-6 at ¶ 11). Then in December of 1991, over eight years after Dr. Grundfest had visited Argonne, and after Cedars had expended millions of dollars and countless hours of research for the development of its method of laser heart surgery, the DOE issued a Determination that it owned the Cedars' patent rights because of the single weekend afternoon use of government equipment at Argonne in 1983 (App. F27-30). The DOE's Determination concerned the ownership of Cedars' U.S. patent application and twelve foreign patents (App. J2). The DOE official who signed the Determination was the head of the very same group that Cedars charged with inequitable conduct in conjunction with its claim that the DOE falsely laid claim to the Cedars laser surgery invention (App. F10 at ¶ 27).

The DOE's Determination under 42 U.S.C. § 5908 of the Federal Non-Nuclear Energy Research and Development Act, as alleged by Cedars, was made without a hearing, without an opportunity for Cedars to take discovery, without an opportunity for Cedars to present argument or cross-examine adverse witnesses. Indeed, the DOE admits the determination was made without any written or published rules at all (App. F10 at ¶ 25). The § 5908 Determination was filed by the DOE in the patent interference proceeding, and was viewed by Cedars as an attempt to dissuade Cedars from pursuing its rights, because Cedars would still have to contend with the DOE Determination even if it prevailed in the expensive patent interference proceeding.

When Cedars challenged the DOE's conduct in its action brought before the District Court, the DOE told the District Court that its § 5908 Determination marked "FINAL"

was in fact "merely preparatory in nature" and that the DOE Determination would subsequently be ruled on by the Board of Patent Appeals and Interferences in the course of dealing with the patent interference proceeding between Cedars and the DOE. Over Cedars' objection that the Board of Patent Appeals and Interferences had no jurisdiction to decide matters under 42 U.S.C. § 5908, the District Court dismissed Cedars' complaint as unripe (App. B8). Notwithstanding the District Court's decision and in confirmation of Cedars' position before the District Court, both the Board of Patent Appeals and Interferences and the Commissioner of Patents and Trademarks ruled that the Board lacked jurisdiction to decide matters under § 5908 (App. A16 at n. 10; C; D; E).

On appeal, the Federal Circuit held that the District Court's holding of lack of finality was error and concluded that "the government's position in this court regarding the finality of the Determination is disingenuous at best . . . " (App. A19). The Federal Circuit found that the DOE's § 5908 Determination was clearly final (App. A19-20). However, the Federal Circuit nevertheless affirmed the District Court's dismissal of Cedars' complaint holding that Cedars had failed to demonstrate direct and substantial hardship under *Abbott Laboratories v. Gardner*, 387 U.S. 135 (1966).

2. The Holding Below Regarding Proof of Hardship

As understood by the Federal Circuit:

> Cedars relies, in main part, on an affidavit of Mr. Paul Yaeger, Cedars' Vice President, as support for its jurisdictional allegations. That

affidavit first describes Yaeger's past success in licensing pending patent applications with third parties. It then continues:

> I am currently involved in third party negotiations relating the Cedars U.S. Patent Application Serial No. 559,430 which is the subject of the . . . December 10, 1991 Determination under § 5908; and . . . the § 5908 Determination has had a pronounced negative impact on such licensing negotiations which I believe will either greatly reduce the royalty income to the Medical Center or prevent the conclusion of any license agreement.

As the government perspicaciously contends, however, Yaeger's assertions relate solely to the effect of the Determination on "current[] . . . third party [licensing] negotiations relating to Cedars['] *U.S. Patent Application*." (emphasis added). The affidavit completely fails to discuss current licensing efforts with respect to Cedars' foreign patent rights. It asserts neither that such negotiations are ongoing or that, if ongoing, have been adversely affected by the Determination and are causing hardship to Cedars. Moreover, even if the Yaeger affidavit could be construed as referencing licensing of foreign patent rights, the conclusory statements do not provide the necessary factual basis to support jurisdiction. Facts must be set forth to demonstrate that the Determination directly

> and substantially interferes with Cedars' foreign licensing efforts. Conclusory statements, standing alone, are insufficient to carry Cedars' burden to prove hardship under the second prong of the *Abbott Laboratories* test.

(App. A24-25).

REASONS FOR GRANTING THE WRIT

1. The Federal Circuit Misapplied *Abbott*, in Conflict with the Court of Appeals for the District of Columbia Circuit

The Federal Circuit has erroneously applied the two-prong test for ripeness (*i.e.*, fitness for judicial resolution and hardship) developed for testing the ripeness of pre-enforcement agency actions to a final, self-enforcing DOE determination. In doing so, the Federal Circuit has come into conflict with the Court of Appeals for the District of Columbia Circuit.

The standard for determining the ripeness of agency actions for judicial review is set out in *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148-149 (1967) (emphasis added; footnote omitted):

> Without undertaking to survey the intricacies of the ripeness doctrine it is fair to say that its basic rationale is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference *until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.*

For Cedars, the DOE's decision has been formalized (it is final), and the effects of that decision have been felt in a concrete way: Cedars' patent rights have been taken from Cedars and vested in the DOE.

In contradistinction to Cedars' situation, the Court in *Abbott* clearly recognized that the specific matter before it was one of "pre-enforcement review" under the Administrative Procedure Act. *Id.* at 141. In *Abbott*, a regulation required drug manufacturers to either change their drug labeling or not change their labeling and risk prosecution and possible criminal sanctions. *Id.* at 152-53. Abbott challenged the regulation *before it was enforced.* For such pre-enforcement review, this Court required the satisfaction of a two-prong test, "requiring us to evaluate the fitness of the issues for judicial decision and the hardship of withholding court consideration." *Id.* at 149.

In Cedars' case, the Federal Circuit found that the DOE's Determination under 42 U.S.C. § 5908 was fit for review. Indeed, the DOE's Determination was a final and concrete application of § 5908 to Cedars' patent rights. Moreover, the § 5908 Determination was self-enforcing: Upon such a determination, "title to such invention shall vest in the United States, and if patents on such invention are issued they shall be issued to the United States . . . ." The Determination, in and of itself, thus worked a forced assignment of Cedars' patent rights. *Cf., Filmtec Corp. v. Hydranautics*, 982 F.2d 1546, 1553 (Fed. Cir. 1992), *cert. denied*, ___ U.S. ___, 126 L.Ed.2d 53, 114 S.Ct. 85 (1993) ("[T]itle to that invention immediately vested in the United States by operation of law [and] . . . the statute [42 U.S.C. § 5908] had divested him of all of his interest. Although all of the formalities of the statute . . . were not complied with, that omission does not change the effect of the law.") Accordingly, Cedars' foreign patents are now owned by the United States, and if the Cedars inventors obtain a U.S. patent, it will be issued not to Cedars (even though Cedars is the entity to which the inventors assigned their application),

but to the United States Government. The confiscation of Cedars' rights to the invention is thus complete, total, unconditional and immediate. There is nothing tentative or provisional about it.

The DOE's determination is as fit for judicial review as it ever will be. The Federal Circuit in finding this issue unripe, failed to recognize the significance of the distinction between a concrete, particularized and self-enforcing agency action such as present here and, on the other hand, a "pre-enforcement" action, such as was present in *Abbott*. Since Cedars challenged the DOE's Determination only *after* the DOE's taking of its patent rights had become final, the specific *Abbott* concerns of avoidance of premature adjudication and abstract disagreements over administrative pre-enforcement acts are simply not applicable. It was thus an error for the Federal Circuit to apply the second, hardship, prong of the *Abbott* ripeness test to a situation where the administrative decision had manifestly "been formalized and its effects felt in a concrete way."

Moreover, Cedars' claim to set aside the DOE's Determination as an unlawful agency action (App. F17 at ¶ 42) was fit for disposition on purely legal grounds, including, *inter alia*, the following:

> (1) That the DOE's Determination was erroneous as a matter of law because 28 U.S.C. § 5908, under which the Determination was purportedly made, does not apply to government acquisitions of title to an invention made by a nonprofit organization, such as Cedars (App. F15-16 at ¶¶ 34-37);

> (2) That Chapter 18 of Title 35 of the United States Code, which governs the case, bars the DOE from asserting title to the invention because the DOE never entered into a funding agreement with any of the plaintiffs (App. F16 at ¶ 36; F18 at ¶ 44(d)); and
>
> (3) That the taking of Cedars' property was in violation of due process, because, *inter alia*, the procedure employed by the DOE was not according to any published rules (App. F10 at ¶ 25).

There was no genuine *factual* dispute about whether or not the DOE followed published rules in making its Determination, nor about whether Cedars fits within the statutory definition of a "nonprofit organization" (App. H2 at ¶ 3), nor about whether anything that transpired between Petitioners and the DOE could possibly support the conclusion that a "funding agreement" existed. All these potentially dispositive issues were ripe to be ruled upon as matters of law.

The Federal Circuit's application of both prongs of the *Abbott* test under these circumstances places that court in conflict with the Court of Appeals for the District of Columbia Circuit which applies *Abbott* differently under similar circumstances. In *Consolidated Rail Corp. v. United States*, 896 F.2d 574, 577-578 (D.C. Cir. 1990) (citations omitted; alteration in the original; emphasis added), the Court of Appeals for the District of Columbia Circuit stated:

> The first, or fitness, part of the *Abbott Labs* test normally requires us to determine whether the issue is "(a) essentially legal, and (b) 'sufficiently final.'" . . . If we have doubts

> about the fitness of the issue for judicial resolution, then we balance the institutional interests in postponing review against the hardship to the parties that will result from delay. Where, however, "there are no significant agency or judicial interests militating in favor of delay, [lack of] 'hardship' cannot tip the balance against judicial review.". . .
>
> In light of our conclusion that this matter is clearly fit to be heard, *we need not consider whether petitioners would suffer any hardship from our postponing its resolution.* Even if we believed that no such hardship would result, the Commission's concession that its decision is "purely legal," and our finding that it is effectively as well as formally "final," would lead us to conclude that it is ripe for review.

Thus, in *Consolidated Rail*, the "hardship" prong of the *Abbott* test was deemed unnecessary to reach or apply; whereas in the case at bar, the "hardship" prong was not only applied but held to be dispositive. There is thus a plain conflict between Courts of Appeals on this point. *See also*, *American Petroleum Institute v. U.S. EPA*, 906 F.2d 729 (D.C. Cir. 1990).

Moreover, if other Courts of Appeals were to explicitly face the issue of the applicability of the *Abbott* two-prong test to final, executed agency decisions, all indications are that those Courts of Appeals would also come into conflict with the Federal Circuit. For example, in *Haitian Refugee Center v. Civiletti*, 503 F.Supp. 442, 469-470

(S.D. Fl. 1980), *aff'd. sub. nom.*, *Haitian Refugee Center v. Smith*, 676 F.2d 1023 (5th Cir. 1982) (last emphasis added), the District Court stated:

> The Supreme Court has outlined a two step process for determining whether a particular case is ripe for adjudication: "The problem is best seen in a twofold aspect, requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Laboratories v. Gardner*, ... However, the court did not intend that every federal court had to apply this two-step procedure in every case; before a court is obligated to explore "the intricacies of the ripeness doctrine," the party suggesting *un*ripeness ought to be able to articulate why the case may be *un*ripe . . . .
>
> Ripeness doctrine has evolved into a "stable and satisfactory" body of law. See generally, K. Davis, Administrative Law Treatise § 21.00 (1980 Supplement). *Generally, it is applied when some party wants to challenge prospective administrative action, and the doctrine assists courts in determining which such challenges to prospective conduct should be entertained. Ripeness doctrine has no application to cases contesting past*

> *administrative action against the very individuals who challenge that action.*

See also, Ali v. INS, 661 F.Supp. 1234 (D.Mass. 1986).

If the Court accepts jurisdiction over this appeal, it will have the opportunity to resolve the conflict between the District of Columbia Circuit and Federal Circuit Courts of Appeals regarding the applicability of the *Abbott* two-prong test to final and enforced agency actions, as well as the opportunity to preempt the likely spread of that conflict to other Courts of Appeals.

2. If The Demonstration of Hardship is a Necessary Predicate to Jurisdiction Over Final Agency Actions, A Governmental Taking of Title to Property Inherently Satisfies That Predicate

Even if the Federal Circuit was correct to apply both prongs of the *Abbott* test and thus to require a demonstration of hardship, the very finding of a final agency action which vested title to property in the Government should, in and of itself, adequately demonstrate that hardship. Any other result would allow governmental agencies to take property without a guarantee of due process. To say that Cedars, having shown that its intellectual property has been finally and unconditionally taken by the Government, must go farther and articulate why its loss is a hardship is rather like saying that a man whose house has been confiscated by the Government does not meet the "hardship" test and cannot have judicial review, unless he goes beyond demonstrating that title to his property has been taken and spells out, under oath, such details as: (1) why one cannot sell, lease or dwell in a house

that now belongs to someone else; and (2) just why it is bad to be homeless.

The importance of private property rights in American jurisprudence is manifest. The Fifth Amendment to the Constitution states: "[N]or shall any person . . . be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation." The taking of property is hardship. Contrary to the Federal Circuit's ruling, no further proof should be required.

The property rights at issue here (patent rights) are of no less import than any other form of property. As stated by this Court in *James v. Campbell*, 104 U.S. 356, 357-358 (1882):

> That the Government of the United States when it grants letters patent for a new invention or discovery in the arts, confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the Government itself without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser, we have no doubt.

Even the Federal Circuit acknowledges that its "own precedent clearly establishes that patent property rights, 'of which the patentee cannot be deprived without due process of law . . . necessarily includes the right 'to license and exploit patents'.' *Patlex Corp. v. Mossignhoff*, 758 F.2d 594, 599, 225 USPQ 243, 246 (citations omitted), *modified*, 771 F.2d

480, 226 USPQ 985 (Fed. Cir. 1985)" (App. A19). And unlike other property, "patent property is a wasting asset, and justice is ill served by delay in final resolution [of patent disputes]." *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1266 (Fed. Cir. 1991).

In this case, the Federal Circuit found that "[e]xpiration of the 30-day period in which to request reconsideration of Energy's Determination [pursuant to 42 U.S.C. § 5908] rendered that decision *final* . . . " (App. A19--20; emphasis added). Since 42 U.S.C § 5908 is (on its face) self-enforcing, the DOE's final Determination means that title to the patent rights at issue have been taken from Cedars and vested in the government. Yet despite this clear and final taking of title to property, the Federal Circuit held, under the *Abbott* two-prong test, that the controversy was not ripe for judicial review because Cedars failed to demonstrate sufficient hardship (App. A26). The Federal Circuit's requirement that hardship be explicitly proven, over and above the fact of a governmental taking of property, constitutes an intolerable roadblock to Cedars' (or any similarly aggrieved party's) Constitutional right to due process.

We do not concede that Cedars, having shown that a final, unconditional taking of title to its patent rights occurred, could properly be required to go farther and present proof to satisfy the "hardship" prong of the *Abbott* test. We nevertheless note that Cedars *did* present such proof, and that if the Federal Circuit did not err in deeming such proof necessary, it erred in finding it insufficient. A brief review of Cedars' hardship proof follows:

1) *Inherent Harm:* In addition to taking Cedars' U.S. patent rights, the DOE by its Determination also took Cedars'

patents in the following countries: Australia, Austria, Belgium, France, Germany, Japan, Luxembourg, Netherlands, Sweden, Switzerland, Liechtenstein, and the United Kingdom (App. J2). The lives of these patents (now vested in the DOE) are lessening year by year. While Cedars waits for an adjudication of its challenge to the Determination, Cedars must incur the costs of paying fees to maintain its patents, or stop payments and allow those patents to expire. And Cedars must continue an expensive interference proceeding regarding the U.S. patent rights, not knowing whether the rights it is fighting over are properly owned by the DOE. Thus the hardship *inherent* from the final Determination is considerable.

2) *Alleged Harm*: Cedars alleged the DOE Determination will delay the availability of laser angioplasty, with various associated costs to the public which Cedars serves (App. F8-9 at ¶ 16). (Congress specifically sought to encourage such public service from not-for-profit institutions. *See,* Internal Revenue Code § 501(c)(3).) Cedars also alleged that it had spent much time, effort and money to practice, develop, disseminate and improve the invention (App. F15 at ¶ 32). These allegations were not factually contradicted by the Government, nor did the District Court's decision purport to resolve any disputed factual issues. To the extent that the Federal Circuit refused to consider these allegations as true, it not only erred, but is apparently in conflict with other Courts of Appeals. *See, Williamson v. Tucker*, 645 F.2d 404, 413 (5th Cir.), *cert. denied*, 454 U.S. 897 (1981) ("[I]f the [district] court's *decision* rests on [the complaint or the complaint supplemented by undisputed facts] —— in which case the court need not decide among conflicting factual positions —— *our review is limited to determining whether the district court's application of the law is correct* . . . .";

emphasis added). Here, the District Court's *decision* was purely legal, apparently accepting Cedars' allegations as true (App. B6-7). The Federal Circuit's review should thus have been limited to the District Court's application of the law.

3) *Evidenced Harm:* All the evidence submitted to the District Court supported a finding of hardship (App. H; I; J). An affidavit of Mr. Paul Yaeger, Cedars' Vice President, stated that "the § 5908 Determination has had a pronounced negative impact on . . . licensing negotiations . . . " There was simply no countervailing evidence, only countervailing conclusory attorney argument (App. A23; K2-4). To the extent that the Federal Circuit required more evidence (or even this much), it is again apparently in conflict with other Courts of Appeals. *See, Ohio National Life Insurance Company v. United States*, 922 F.2d 320, 327 n.7 (6th Cir. 1990) ("That the burden of proof is always on the plaintiff to show that a federal court has jurisdiction over the subject matter, does *not* mean that a defendant, *without any proof on his part*, can put the plaintiff to proof by affidavit of jurisdictional facts sufficiently alleged in the complaint"; emphasis added).

It is astonishing that this inherent, alleged and evidenced harm was not held sufficient to render the dispute ripe, and allow exercise of jurisdiction. Such a holding would be astonishing even if the Federal Circuit were right in its view that the *Abbott* test applies and requires some specific and particularized showing of "hardship" beyond that which naturally and inherently arises from a governmental taking like that at issue here.

What is most disturbing, from a due process standpoint, about the Federal Circuit's ruling is that it will

prevent plaintiffs in many cases from *ever* obtaining judicial review of a governmental taking —— even where, as here, that taking is a final, complete and unconditional divestiture of title to the plaintiff's property —— because it will be impossible to make a sufficiently specific, particularized showing of the requisite "hardship."

For example, the Government might take a plaintiff's patent rights at an early stage, before the plaintiff has negotiated any licenses, so that a market value for the rights has not been established. The plaintiff in such a case might allege that the taking deprived him or her of title to property —— an allegation which is *not* sufficient to establish the "hardship" necessary for jurisdiction under the Federal Circuit's view —— but the plaintiff could not allege, in any detail or with any exactitude, who or what kind of licensee would have come forward but for the taking, or how much that licensee would have paid for a license had the taking not occurred. What is worse, such a plaintiff would have little hope of marshalling proof of this kind *after* the taking has happened, for then he or she will have nothing to offer potential licensees, and they will correspondingly lack any reason to approach the plaintiff; and of course they will have no reason at all to offer him royalties or other license terms which might arguably establish a market value and prove the economic value of the taken rights.

Hence, if this Court lets stand the Federal Circuit's jurisdictional requirement for proof of direct and substantial hardship (over and above that which is inherent in a taking of title to property), a party in Cedars' position might *never* be entitled to judicial review of the determination that took its property. How, as a practical matter, can a party in Cedars' position be expected to go any farther than Cedars already has

gone to demonstrate concrete and specific harm? Manifestly, such a party is not in a position to conduct ongoing negotiations with potential licensees once it has been told that the subject rights no longer belong to it and are now owned by the Government. And even if a third person would, for some unimaginable reason, still be motivated to want a license from a party which no longer owned any licensable interest in the invention, how would the potential licensor (*i.e.*, the party in Cedars' position) know the state of the potential licensee's mind, so as to be able to say that it was the Government's taking, and not something else, that caused the licensing not to happen?

If the Federal Circuit is sustained by this Court in its rigorous insistence on a specific and particularized showing of hardship to support judicial review, the result, at least sometimes and probably often, will be that a party finally deprived of property rights will be foreclosed from judicial review of the claim that that taking was wrongful. The Federal Circuit's position therefore raises the possibility of a complete denial of due process.

It should be noted, finally, that the difficulties of showing specific and particularized hardship from a taking of property are not peculiar to patent cases. Similar difficulties can arise in *any* case where the taking occurs before a market value for the taken rights has been established, as, for example, where the rights are of a unique character and the taking occurs before the plaintiff's effort to exploit them has begun, or before it has progressed far enough for potential purchasers, lessees or licensees to be discussing price.

Under Constitutional standards, a governmental agency's final taking of property rights, alone, is (or at least should be) a sufficient hardship to support subject matter jurisdiction over claims arising from that taking. By accepting jurisdiction over this question, this Court can assure that the application of the test for ripeness is applied in a manner consistent with due process and other Fifth Amendment considerations.

CONCLUSION

Granting this petition for certiorari will allow the Court to resolve a conflict between the Circuits, as well as to resolve important due process and private property issues. Should Petitioners be correct in urging that the Federal Circuit erred in applying the *Abbott* pre-enforcement test to a final and enforced agency action, and further erred in requiring a hardship showing in addition to the taking of property, this matter should be remanded to the District Court for a determination on the merits.

DATED: March 11, 1994

Respectfully submitted,

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

92-1410

CEDARS-SINAI MEDICAL CENTER, WARREN S. GRUNDFEST, M.D., JAMES S. FORRESTER, M.D., and FRANK LITVACK, M.D.,
Plaintiffs-Appellants,

v.

JAMES D. WATKINS, Secretary,
United States Department of Energy,
Defendant-Appellee.

Coe A. Bloomberg, Lyon & Lyon, of Los Angeles, California, argued for plaintiffs-appellants. With him on the brief was *David A. Randall*.

William C. Bergmann, Attorney, Commercial Litigation Branch, Department of Justice, of Washington, D.C., argued for defendant-appellee. With him on the brief were *Stuart E. Schiffer*, Acting Assistant Attorney General and *Vito J. DePietro*, Director. Also on the brief was *Thomas J. Byrnes*, Assistant Director, Department of Justice, of counsel.

Appealed from: U.S. District Court for the Central District of California

Judge Davies

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

92-1410

CEDARS-SINAI MEDICAL CENTER, WARREN S. GRUNDFEST, M.D., JAMES S. FORRESTER, M.D., and FRANK LITVACK, M.D.,
Plaintiffs-Appellants,

v.

JAMES D. WATKINS, Secretary,
United States Department of Energy,
Defendant-Appellee.

DECIDED: December 13, 1993

Before ARCHER, MICHEL and CLEVENGER, Circuit Judges.

CLEVENGER, Circuit Judge.

Cedars-Sinai Medical Center, a non-profit corporation, and Drs. Grundfest, Forrester, and Litvack, all of whom are employed at the Medical Center (collectively Cedars), appeal from the May 19, 1992 order of the United States District Court for the Central District of California[1] dismissing

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[1] *Cedars-Sinai Medical Ctr. v. Watkins*, No. CV-92-0154-JGD (C.D. Cal. May 19, 1992) (order dismissing action without prejudice).

Cedars' cause of action without prejudice for lack of subject matter jurisdiction on ripeness grounds. After concluding that we have statutory jurisdiction over this appeal, we affirm the district court's dismissal.

I

In June 1983, Dr. Grundfest conducted certain experiments in the area of laser angioplasty[2] at the Argonne National Laboratory (Argonne), a government-owned facility operated by the University of Chicago under contract with the United States Department of Energy (Energy). After the work at Argonne, Grundfest et al. on December 8, 1983 filed U.S. Patent application Serial No. 06/559,430 entitled "Method of Medical Treatment Using an Excimer Laser on Organic Tissue" with Cedars as the assignee thereof. Foreign patents encompassing the subject matter of Grundfest's original U.S. application have since been procured by Cedars in at least eleven foreign countries.

On January 9, 1984, Dr. Gruen, an employee at Argonne with whom Grundfest had performed his experiments, filed U.S. Patent application Serial No. 06/569,088 claiming the same subject matter as Grundfest's application. U.S. Patent No. 4,686,979, entitled "Excimer Laser Phototherapy for the Dissolution of Abnormal Growth," ultimately issued to Gruen et al. on August 18, 1987 from a continuation-in-part of the original application,[3] and is presently owned by the United States as assignee.

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[2] This technique utilizes lasers in the surgical reconstruction of blood vessels.

[3] Application Serial No. 06/702,569, filed by Gruen et al. on February 19, 1985, spawned the patent as a continuation-in-part of application Serial No. 06/569,088, which had been abandoned.

The same subject matter was also claimed by a third party, Mr. Ralph Linsker, who filed U.S. Patent application Serial No. 07/198,424 entitled "*In vivo* Ablation of Blood Vessel Lesions Employing Laser Energy at a Wavelength of 210 to 320 Nanometers" on May 25, 1988.

On September 10, 1991, as a result of Cedars' efforts, Interference No. 102,459 was declared between Grundfest (Senior Party),[4] Gruen, and Linsker, wherein priority of invention under 35 U.S.C. § 102(g) will be initially determined by the Board of Patent Appeals and Interferences (Board).

On December 10, 1991, Energy served upon Cedars a document entitled "Determination Under 42 U.S.C. § 5908" (Determination) which asserted title to any invention Grundfest may have made. The Determination stated, in part, that the Secretary of Energy

> [had] determined that the activities of Grundfest . . . in relation to the invention were carried out with a contribution by the Government of the use of Government facilities, equipment, materials and allocated funds and that the invention is related to the arrangement or understanding under which the participants in the research operated and the work they performed and therefore that the invention, if it was made by Grundfest

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[4] Grundfest et al.'s application Serial No. 07/205,611, which was involved in the Interference, was accorded the benefit of the original 06/559,430 application.

> . . . , was made in the manner specified in 42 U.S.C. [§] 5908.

The Determination thus implicitly concluded that "title to [any] invention [made by Grundfest et al.] shall vest in the United States." 42 U.S.C. § 5908. The Determination also provided that any request by Cedars for reconsideration of the administrative action "shall be submitted to [Energy] within thirty (30) days" of issuance. Cedars, however, did not request reconsideration.[5] After expiration of the 30-day period, Energy issued a declaration of finality on February 4, 1992 informing the Board that the Determination was a final agency action.

Meanwhile, Cedars had filed suit in the United States District Court for the Central District of California asserting two causes of action. In its first cause of action, Cedars sought to set aside the Determination under the Administrative Procedure Act (APA), 5 U.S.C. §§ 701-706 (1988), as invalid and without force or effect because, *inter alia:* The Determination violated Cedars' Fifth Amendment right to due process; it was generated in a procedurally defective manner; and the issuance thereof exceeded the Secretary of Energy's statutory authority. Cedars' second cause of action sought a declaratory judgment under 28 U.S.C. § 2201 (1988) on several issues: Whether the doctrines of laches, waiver and estoppel bar the government from asserting title to Cedars' invention under section 5908; whether section 5908 applies to Cedars; whether section 5908

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[5] On appeal, neither party addresses the potential effect of Cedars' failure to exhaust its available administrative remedies of the federal courts' authority to entertain this appeal, nor did the district court address this issue. We also need not address this issue, however, in light of our conclusion that this case fails to satisfy the strict requirements of Article III, § 2 of the U.S. Constitution.

is superseded by chapter 18 of Title 35 of the United States Code, 35 U.S.C. §§ 200-212 (1988) (35 U.S.C. ch. 18); and whether the Determination was unlawfully issued.

After considering Cedars' complaint and the parties' various motions, the district court granted the government's motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure.[6] The court concluded that the entire controversy between the parties was not ripe for adjudication, reasoning that the Board could reach a result in the pending Interference that would eliminate any need to address Cedars' arguments:

> [T]he issues are not fit for judicial decision since the interference action is still pending and the Board has not yet issued an opinion . . . . It is possible that the Board could decide that the patent belongs to the Gruen group, which currently holds the patent . . . [or to] Linsker . . . [in which case Energy's] Determination would be of absolutely no consequence because it only says that in the event the Board awards the patent to the Grundfest group, the United States would still own the patent . . . .

The court found insufficient to render the case ripe for adjudication Cedars' allegation that the Determination had immediately impacted Cedars' rights by placing a cloud upon

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[6] The government had also filed a motion to dismiss under Rule 12(b)(6) for failure to state a claim upon which relief could be granted. The district court correctly refused to entertain this motion, however, concluding that it was untimely made after the government had already filed a responsive pleading (answer) to Cedars' complaint. *See* Fed. R. Civ. P. 12(b).

the title to its foreign patents, thereby affecting Cedars' ability to successfully license its intellectual property. Cedars timely appealed the district court's dismissal to this court. The government then filed a motion to dismiss the appeal for lack of subject matter jurisdiction, arguing that the appeal belonged in the United States Court of Appeals for the Ninth Circuit. This motion is presently pending, Cedars' suggestion for an in banc hearing on this issue having been declined on October 7, 1992.

II

In response to the government's motion to dismiss, we turn first to the issue of whether this court possesses statutory jurisdiction over the subject matter of this appeal before reviewing arguments on the constitutional ripeness issue.

Our jurisdiction is circumscribed by statute, and is specifically limited to certain catalogued fields of the law. Pertinent to this case, 28 U.SC. § 1295(a)(1) (1988) grants to this court exclusive jurisdiction over an appeal from a federal district court "if the jurisdiction of that court was based, in whole or in part, on [28 U.S.C. § 1338 (1988)]." Thus, under section 1295(a)(1), the determination of whether this court has jurisdiction to hear an appeal is necessarily driven by whether a district court's jurisdiction was based at least in part on 28 U.S.C. § 1338. This presents a pure question of law. *See Speedco, Inc. v. Estes*, 853 F.2d 909, 911, 7 USPQ2d 1637, 1639-40 (Fed. Cir. 1988); *Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544, 1550, 3 USPQ2d 1241, 1245-46 (Fed. Cir. 1987), *vacated*, 486 U.S. 800, 7 USPQ2d 1109 (1988).

28 U.S.C. § 1338(a) reads, in pertinent part: "The district courts shall have original jurisdiction of any civil action *arising under* any Act of Congress *relating to*

patents . . . ." (emphasis added). In determining whether section 1338(a) is satisfied, the failure of a complaint to reference section 1338 is not dispositive. *Morganroth v. Quigg*, 885 F.2d 843, 846, 12 USPQ2d 1125, 1127 (Fed. Cir. 1989). Rather, "[t]he critical inquiry is whether in fact the complaint asserted a claim arising under the patent laws." *Id.*, 12 USPQ2d at 1127.

In *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 7 USPQ2d 1109 (1988), the Supreme Court interpreted the "arising under" language of section 1338(a) in the same fashion as that of 28 U.S.C. § 1331 (1988), which governs the federal district courts' original jurisdiction over "federal questions." The Court thereby incorporated the principles underlying the "well pleaded complaint" rule into the root of our patent law jurisdiction, stating:

> [Section] 1338 jurisdiction . . . extend[s] only to those cases in which a well-pleaded complaint establishes either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims.

486 U.S. at 808-09, 7 USPQ2d at 1113 (citations omitted). Either determination under *Christianson* requires that this court identify the statute(s) pursuant to which the present causes of action are brought.

Cedars' second cause of action seeks a declaratory judgment that the Energy Determination is invalid on several

grounds.[7] Though on its face, the complaint seeks to raise issues under, *inter alia*, Title 35, it is settled law that a plaintiff may not satisfy the well-pleaded complaint rule simply by filing a declaratory judgment complaint that on its face requires resolution of a question of patent law if a direct

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[7] Cedars' first cause of action directly challenges the validity of the Determination under the APA. Cedars argues that for such an APA claim, the court must examine the underlying statute which the court has been asked to construe to determine whether jurisdiction exists. As support for its position, Cedars cites *Morganroth*, 885 F.2d at 846, 12 USPQ2d at 1127, and *Animal Legal Defense Fund v. Quigg*, 900 F.2d 195, 196, 14 USPQ2d 1485, 1486 (9th Cir. 1990) (Ninth Circuit concluded that section 1338 jurisdiction existed based on claim that Commissioner of Patents lacked authority under Title 35 to rule that animals are patentable subject matter, even though wholly independent claim challenging only the procedural regularity of the Commissioner's rule was brought), *transferring case to* 932 F.2d 920, 18 USPQ2d 1677 (Fed. Cir. 1991) (affirming on merits without comment on jurisdictional issue). Cedars concludes that the statutes underlying its APA claim include 35 U.S.C. ch. 18 and 42 U.S.C. § 5908 and therefore its APA claim arises under laws relating to patents regardless of whether all of Cedars' APA claims implicate a patent statute.

We first question whether the *Christianson* Court's statement that "a claim supported by alternative theories in the complaint may not form the basis for [section] 1338(a) jurisdiction *unless patent law is essential to each of those theories*," 486 U.S. at 810, 7 USPQ2d at 1114 (citations omitted) (emphasis added), undermines Cedars' reliance on *Animal Legal Defense Fund* because Cedars' APA claims, *inter alia*, also challenge the Determination on a purely procedural basis. We additionally question whether Cedars' alleged authority is properly viewed in light of the principles articulated in *Wang Labs., Inc. v. Applied Computer Sciences. Inc.*, 958 F.2d 355, 358, 22 USPQ2d 1055, 1057-58 (Fed. Cir. 1992) (under *Christianson*, when another circuit has determined that case falls within Federal Circuit's exclusive jurisdiction, this court's "jurisdictional inquiry is at an end" if we "can find the transfer decision plausible"), and *Xeta. Inc. v. Atex. Inc.*, 852 F.2d 1280, 1281, 7 USPQ2d 1471, 1472 (Fed. Cir. 1988) (under *Christianson*, when one appellate court transfers case, its "jurisdictional decision . . . is the law of the case"). We need not fully address this argument, however, since we conclude that we clearly have statutory jurisdiction over this case under Cedars' declaratory judgment action.

complaint for redress would not otherwise invoke the patent laws. As we held in *Speedco*, when faced with a declaratory judgment, this court employs the principles articulated in *Franchise Tax Bd. v. Construction Laborers Vacation Trust*, 463 U.S. 1, 16 (1983) (citing *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667 (1950)), in order to determine whether section 1338 jurisdiction exists. We thus apply the well-pleaded complaint rule, not to the declaratory judgment complaint, but to the hypothetical action that the declaratory judgment defendant would otherwise have brought directly against the declaratory judgment plaintiff. *Speedco*, 853 F.2d at 912, 7 USPQ2d at 1640.

After constructing a hypothetical complaint that otherwise would have been filed by the declaratory judgment defendant, this court's jurisdictional onus is then to determine both under which federal statute(s) the hypothetical cause of action would have "aris[en]," and whether those federal statute(s) "relat[e] to" patents, while staying ever loyal to the Supreme Court's guidance in *Christianson*, 486 U.S. at 808, 7 USPQ2d at 1113.

In the present case, the hypothetical cause of action is one to enforce the Determination: an injunctive action against Cedars to enforce Energy's rights as declared in the Determination, or in the government's words, "an action for the forced assignment (or issuance) of the rights to the patent application in question" to the Secretary of Energy. This hypothetical cause of action at least in part "aris[es] under" the substantive statute of 42 U.S.C. § 5908, since a district court would be required to address, *inter alia*, whether section 5908 actually encompasses Cedars' experimentation at

Argonne.[8] *See also* 28 U.S.C. § 1361 (1988) (possible action against Commissioner under general federal mandamus provision).

The government, however, argues that section 5908 cannot "relat[e] to" patents because it is concerned solely with title, ownership, and assignment issues which are merely contract issues over which this court lacks exclusive jurisdiction. Though we agree that this court generally lacks jurisdiction over a simple contractual dispute involving construction of contract terms familiar to the patent law, *see. e.g.*, *American Tel. & Tel. Co. v. Integrated Network Corp.*, 972 F.2d 1321, 23 USPQ2d 1918 (Fed. Cir. 1992) (presence of contractual terms "invention," "made or conceived," and "make or conceive" insufficient to permit removal of case from state to federal court); *Ballard Medical Prods. v. Wright*, 823 F.2d 527, 530, 3 USPQ2d 1337, 1339 (Fed. Cir. 1987) (that patent issues are relevant to resolution of a contract dispute "cannot possibly convert a suit for breach of contract into one 'arising under' the patent laws"); *Beghin-Say Int'l. Inc. v. Ole-Bendt Rasmussen*, 733 F.2d 1568, 1570-71, 221 USPQ 1121, 1123 (Fed. Cir. 1984) (dispute over agreements that may assign future patent applications does not convert conflict into one under federal patent laws),

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[8] Cedars' argument that 35 U.S.C. ch. 18 is a necessary element to its declaratory judgment claim evidences a failure to concentrate on the hypothetical action, because chapter 18 of Title 35 would be invoked only if Cedars, in defending the hypothetical enforcement action, challenged the validity and applicability of 42 U.S.C. § 5908, and the scope thereof as preempted by 35 U.S.C. ch. 18. An alternate legal defense raising a question of patent laws however, is insufficient to confer jurisdiction on this court, since Cedars' right to relief would not necessarily depend on resolution of the question concerning 35 U.S.C. ch. 18. *See Christianson*, 822 F.2d 1544, 1550, 3 USPQ2d 1241, 1249 (Fed. Cir. 1987), *vacated*, 486 U.S. 800, 7 USPQ2d 1109 (1988); *Christianson*, 486 U.S. at 808, 810, 7 USPQ2d at 1113, 1114.

and although we agree that "when an invention was conceived may be more a question of common sense than of patent law," *American Telephone*, 972 F.2d at 1324, 23 USPQ2d at 1920, we cannot escape the fact that section 5908, whether or not concerned purely with ownership, is an Act of Congress and therefore presents a case clearly distinguishable from those concerning whether a contract dispute belongs in state or federal court.

Moreover, the Act of Congress in the present case clearly "relat[es] to" patents. 42 U.S.C. § 5908(a)[9] is entitled "Vesting of title to invention and issuance of patents to United States; prerequisites," and may only be invoked

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[9] Section 5908 reads, in part:

Chapter 74 —— Nonnuclear Energy Research and Development

* * *

§ 5908. Patents & inventions

(a) Vesting of title to invention and issuance of patents to United States; prerequisites

> Whenever any invention is made or conceived in the course of or under any contract of the Secretary [of Energy], . . . and the Secretary [of Energy] determines that ——
>
> > (1) the person who made the invention was employed . . . to perform research . . . ; or
> >
> > (2) the person who made the invention was not employed . . . to perform research . . . , but the invention is nevertheless related to . . . the work . . . he was employed . . . to perform . . . [,]
>
> title to such invention shall vest in the United States, and if patents on such invention are issued they shall be issued to the United States, unless in particular circumstances the Secretary [of Energy] waives all or any part of the rights of the United States to such invention in conformity with the provisions of this section.

"whenever any invention is made or conceived in the course of . . . any contract of the Secretary [of Energy]." *See also* 42 U.S.C. § 5908(m)(3), (4) (respectively defining "made" and "invention"). Further, once either of the statutory requirements in section 5908(a) (1) & (2) are satisfied, "title to such invention shall vest in the United States, and if patents on such invention are issued they shall be issued to the United States . . . ." We must reject any argument to the effect that a statute that in essence instructs the Commissioner to issue a patent to the United States, rather than to the named inventor and thus concerns the administrative functioning of the Commissioner and the Patent & Trademark Office (PTO), is not "relat[ed] to" patents. *See Morganroth v. Quigg*, 885 F.2d 843, 12 USPQ2d 1125 (Fed. Cir. 1989) (jurisdiction over case involving review of Commissioner's order on petition to revive an abandoned application); *Wyden v. Commissioner of Patents & Trademarks*, 807 F.2d 934, 231 USPQ 918 (Fed. Cir. 1986) (jurisdiction to review Commissioner's refusal to award passing grade on registration examination under 35 U.S.C. § 32 (1988)); *Dubost v. United States Patent & Trademark Office*, 777 F.2d 1561, 227 USPQ 977 (Fed. Cir. 1985) (jurisdiction over mandamus action challenging PTO's administrative determination denying filing date to application because check accompanying application was unsigned); *cf.* 35 U.S.C. § 145 (1988) (civil action against commissioner to obtain patent).

We conclude that 42 U.S.C. § 5908 is "an Act of Congress relating to patents," and therefore that Cedars' complaint conferred statutory jurisdiction upon the district court based in part on section 1338. This court thus has statutory jurisdiction to review the district court's decision. *See Wyden*, 807 F.2d at 941-42, 231 USPQ at 924-25 (Markey, C.J., dissenting) (predicting that court's holding in banc that it had jurisdiction over administrative matter in PTO

would require taking jurisdiction over action under 42 U.S.C. § 5908); *cf. Alco Standard Corp. v. Tennessee Valley Auth.*, 808 F.2d 1490, 1 USPQ2d 1337 (Fed. Cir. 1986) (suit under 16 U.S.C. § 831r against the Tennessee Valley Authority for reasonable compensation for patent infringement is based on section 1338(a) jurisdiction), *cert. dismissed*, 483 U.S. 1052 (1987). The government's motion to dismiss the appeal is denied.

III

When reviewing a district court's conclusion that the causes of action in a case are not ripe for adjudication, and therefore are beyond the Article III jurisdiction of the federal courts, this court applies the law of the regional circuit in which the district court sits. *Molins PLC v. Quigg*, 837 F.2d 1064, 1066, 5 USPQ2d 1526, 1527 (Fed. Cir.), *cert. denied*, 486 U.S. 1055 (1988); *cf. Minnesota Mining & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 672 & n.3, 18 USPQ2d 1302, 1304 & n.3 (Fed. Cir. 1991) (Federal Circuit law governs review of decision to dismiss infringement suit based solely on existence of pending interference when justiciability of controversy is not in question). The United States Court of Appeals for the Ninth Circuit reviews *de novo* a dismissal under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction. *Love v. United States*, 915 F.2d 1242, 1245 (9th Cir. 1989). However, in the context of a ripeness determination, "[t]he district court's factual findings on jurisdictional issues must be accepted unless clearly erroneous." *Winter v. California Medical Review, Inc.*, 900 F.2d 1322, 1325 (9th Cir. 1990); *see also Hamlet v. United States*, 873 F.2d 1414, 1416 (Fed. Cir. 1989).

IV

The constitutional doctrine of ripeness is succinctly delineated in *Abbott Labs. v. Gardner*, 387 U.S. 136 (1967):

> [The] basic rationale [of the ripeness doctrine] is to prevent courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties. The problem is best seen in a twofold aspect, requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.

Id. at 148-49.

The Supreme Court thus requires application of a two-part test to determine whether a case is ripe for judicial action: First, whether the issues are fit for judicial —— that is, whether there is a present case or controversy between the parties, *see Lake-Carriers' Ass'n v. MacMullan*, 406 U.S. 498, 506 (1972); *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 977, 28 USPQ2d 1124, 1126 (Fed. Cir. 1993); and second, whether there is sufficient risk of suffering immediate hardship to warrant prompt adjudication —— that is, whether withholding judicial decision would work undue hardship on the parties, *MacMullan*, 406 U.S. at 506; *Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 200-01 (1983) (quoting *Abbott Labs.*, 387 U.S.

at 149). Both prongs must be satisfied before an Article III court may apply its adjudicative powers to a case's merits. *See Western Oil & Gas Ass'n v. Sonoma County*, 905 F.2d 1287, 1291 (9th Cir. 1990) (Ninth Circuit inquires whether "the controversy generated is essentially legal in nature or whether further factual amplification is necessary [and] . . . assess[es] potential hardship to the parties if review is denied"), *cert. denied sub nom. Western States Petroleum Ass'n v. Sonoma County*, 498 U.S. 1067 (1991).

A

With respect to the first prong of the *Abbott Laboratories* test, the government argues, *inter alia*, that the case is not ripe for adjudication because the issues raised are identical to those pending before the Board, and were the Board to conclude that a party other than Grundfest was, in law, the first to invent the subject matter of the count, Cedars would have no property on which to base a challenge to the Determination.[10] The government also argues that the administrative Determination was not a final agency action which is ripe for judicial action, but rather is "merely preparatory in nature," serving as a prerequisite for Energy's assertion of rights to the invention. The government supports

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[10] Relevant to this argument, we note that both the Board and the Commissioner have adopted the position that the PTO lacks the authority during an interference to decide the ownership question presented by 42 U.S.C. § 5908, because the Board is authorized by 35 U.S.C. § 7 (1988) to decide only patentability and priority issues. *See Gruen v. Linsker*, Interf. No. 102,459, slip op. at 7-8 (Bd. Pat. Apps. Interfs. Feb. 2, 1993) (Paper No. 79); *Gruen v. Linsker*, Interf. No. 102,459, slip op. at 6-8 (Comm'r Op. May 24, 1993); *see also Gruen v. Linsker*, Interf. No. 102,459, slip op. at 39-41 (PTO Aug. 20, 1992) (Examiner-in-Chief 's decision on preliminary motions); 35 U.S.C. § 135(a) (1988) (Interferences).

its second argument with the fact that the Determination itself permitted Cedars to request reconsideration from Energy. The government further argues that no controversy over the Determination can be ripe for adjudication until it takes steps to enforce its rights under the Determination, notwithstanding any possible advance impact that the Determination may have on Cedars because of the reaction of third parties to the Determination. In short, the government contends that it has sole control over the time at which Cedars' complaint becomes ripe.

With respect to its domestic patent rights, Cedars contends that the complaint is justiciably alive notwithstanding the ongoing Interference because of the possibility that Cedars will prevail before the Board. Citing 13A Charles A. Wright et al., *Federal Practice & Procedure* § 3533.1, at 220-21 (1984 & Supp. 1993) and cases cited therein, Cedars argues that its suit remains justiciable "despite a strong probability that a mooting event will occur." We need not dispute that an otherwise justiciable case or controversy may remain so notwithstanding the possibility of a subsequent mooting event. That proposition, however, is irrelevant to the circumstances of this case because Cedars has yet to demonstrate the existence of such a case or controversy.

As of this moment with respect to Cedars' domestic patent rights, the effects of the Determination have yet to be felt in any concrete sense. *Abbott Labs.*, 387 U.S. at 148-49. This is so with regard to both causes of action pleaded in Cedars' complaint. Moreover, due to the pending Interference, judicial resolution of the issues presented would not in any way alleviate the current cloud over Cedars' domestic patent rights, since the overarching question of which party to the Interference will eventually have the right to exclude others from making, using, or selling the technique of laser

angioplasty would remain. Were the Board to conclude that a party other than Grundfest should prevail in the Interference, any decision by the federal courts regarding the efficacy of the Determination would have absolutely no effect with respect to Cedars' domestic patent rights. On the record before this court, we must conclude that based on Cedars' domestic patent rights alone, review of the present case is barred by both Article III and the discretionary prudential consideration of conservation of judicial resources. *See* 13A Wright et al., *supra*, § 3532.1, at 115, 118 n.9; § 3532.2, at 146-47. *Compare Minnesota Mining & Mfg.*, 929 F.2d at 674, 18 USPQ2d at 1305-06 (mere possibility of mooting event in interference, without more, is insufficient reason to dismiss infringement suit). Cedars has not argued that it has domestic property rights other than its rights to the Grundfest application that presumably would be subject to impairment by the existence of the Determination irrespective of the existence of the ongoing Interference. *See* 42 U.S.C. § 5908(m)(4) (as used in section 5908, term "invention" encompasses any invention or discovery, "whether patented or unpatented").

Cedars next argues that the case is ripe for adjudication because the Determination has had an immediate adverse effect on its ability to license its foreign patents. In this regard, Cedars' contention relates to both of its causes of action. According to Cedars, the outcome of the Interference cannot affect its foreign patent rights because the issue before the Board is priority of invention, an issue which is irrelevant under the pertinent first-to-file foreign patent laws and which cannot by itself affect the issue of who first *filed* the application for patent. Cedars further argues that the case is ripe because the issues of statutory construction and interpretation regarding the scope of sections 5908 and 35 U.S.C. ch. 18 are purely legal, and therefore will not benefit

from further factual development. We agree that Cedars has satisfied the "fitness" portion of the test in *Abbott Laboratories*.

First, our precedent clearly establishes that patent property rights, "of which the patentee cannot be deprived without due process of law. . . . necessarily includ[e] the right 'to license and exploit patents.'" *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599; 225 USPQ 243, 246 (citation omitted), *modified*, 771 F.2d 480, 226 USPQ 985 (Fed. Cir. 1985).

Though both Cedars' complaint and the Determination itself fail to mention explicitly that Energy is asserting right and title to Cedars' foreign patent rights,[11] this omission is not fatal to Cedars' position. Without passing on the merits of the government's position, it is uncontroverted by the government on appeal that it understands the Determination to assert title over the foreign patents: "As used in 42 U.S.C. § 5908, 'title' includes both foreign and domestic patent rights." Under such circumstances, the Federal Rules of Civil Procedure are quite permissive in permitting a party to amend its complaint to conform to the evidence and to the positions taken at trial. *See* Fed. R. Civ. P. 15(b) ("When issues not raised by the pleadings are tried by express or implied consent of the parties, they shall be treated in all respects as if they had been raised in the pleadings. . . .").

We also conclude that the government's position in this court regarding the finality of the Determination is disingenuous at best, being wholly at odds with its representations to the Board. Expiration of the 30-day period in which to request reconsideration of Energy's Determination

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[11] In its complaint, Cedars only alleges (i) the taking of its property by the United States' wrongful assertion of title to its invention, and (ii) its substantial investment abroad by pursuing patent rights in other countries.

rendered the decision final, as Energy explicitly represented to the Board during the Interference. Moreover, even assuming that the administrative Determination is not final in the traditional sense, it is nevertheless capable of adversely influencing Cedars' foreign patent rights, even in the absence of any further action from Energy on the issue. If, for example, others refuse to contract with Cedars because of their fear that the Determination abrogates Cedars' ownership of the foreign patents, the Determination will have actual effects without any government effort to enforce its terms. In this sense, the government's position wholly ignores the potential practical effects on Cedars' property rights of the mere existence of the Determination, even if only "preparatory," regardless of any future enforcement efforts by Energy. *See Abbott Labs.*, 387 U.S. at 149 (requirement of finality determined "in a pragmatic way"); *California. Dep't of Educ. v. Bennett*, 833 F.2d 827, 833 (9th Cir. 1987) (same). Furthermore, there is no suggestion that failure to request reconsideration prevents Cedars from now challenging the administrative action in court. *See supra*, note 5.

We thus conclude that the district court's conclusion that Cedars failed to meet the first prong of *Abbott Laboratories* was error, since the fact that the Interference is still pending is immaterial to Cedars' foreign patent rights and therefore extraneous to consideration of whether the case regarding Cedars' foreign patent rights is ripe.

B

Regarding the "hardship" prong of *Abbott Laboratories*, the procedural posture of this case raises "the central concern (of the ripeness) doctrine [of] whether the case involves uncertain or contingent future events that may

not occur as anticipated, or indeed may not occur at all." 13A Wright et al., *supra*, § 3532, at 112 (1984).

Paragraph 39 of Cedars' complaint stated that:

> (Cedars) will suffer irreparable harm for which they lack an adequate remedy at law, for reasons including the following: Difficulty in disseminating the technology to which the invention relates due to doubts on the part of physicians and surgeons, hospitals, potential manufacturers, financiers, consultants, potential licensees and others as to whether [Cedars] ha[s] the right to practice, disseminate and otherwise deal with that technology.[12]

Cedars argues that this allegation in its complaint satisfied the hardship prong of *Abbott Laboratories* because its allegation that the Determination clouds the title to its foreign patents, impairing its ability to license those patents, should be accepted as true and construed in a light most favorable to Cedars for purposes of reviewing a Rule 12(b)(1) dismissal, and because it submitted documentation with its complaint supporting its allegations that it is suffering immediate and substantial hardship abroad. We cannot accept either of Cedars' positions.

The burden of establishing jurisdiction in the district court lies with the party seeking to invoke the court's jurisdiction. *KVOS, Inc. v. Associated Press*, 299 U.S. 269, 278 (1936); *see Farmers Ins. Exch. v. Portage La Prairie Mut. Ins. Co.*, 907 F.2d 911, 912 (9th Cir. 1990); *see also Reynolds v. Army & Air Force Exch. Serv.*, 846 F.2d 746,

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[12] These allegations were specifically denied in the government's answer to Cedars' complaint.

748 (Fed. Cir. 1988). If a Rule 12(b)(1) motion simply challenges the court's subject matter jurisdiction based on the sufficiency of the pleading's allegations —— that is, the movant presents a "facial" attack on the —— then those allegations are taken as true and construed in a light most favorable to the complainant. *See Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974) (case dismissed upon facial attack on complaint, without consideration of any extrinsic evidence); 2A James W. Moore et al., *Moore's Federal Practice* ¶ 12.07[2.-1], at 12-51 to -52 (1993).

If the Rule 12(b)(1) motion denies or controverts the pleader's allegations of jurisdiction, however, the movant is deemed to be challenging the factual basis for the court's subject matter jurisdiction. *Trentacosta v. Frontier Pac. Aircraft Indus., Inc.*, 813 F.2d 1553, 1558-59 (9th Cir. 1987); 5A Charles A. Wright & Arthur R. Miller, *Federal Practice & Procedure* § 1363, at 456-57 (1990). In such a case, the allegations in the complaint are not controlling, *KVOS*, 299 U.S. at 277-79; *Trentacosta*, 813 F.2d at 1559; *Thornhill Publishing Co. v. General Tel. & Elecs. Corp.*, 594 F.2d 730, 733 (9th Cir. 1979); 5A Wright & Miller, *supra*, § 1363, at 457-58, and only uncontroverted factual allegations are accepted as true for purposes of the motion. *Gibbs v. Buck*, 307 U.S. 66, 72 (1939); 5A Wright & Miller, *supra*, §§ 1350, 1363, at 219-20, 457. All other facts underlying the controverted jurisdictional allegations are in dispute and are subject to fact-finding by the district court.[13] 2A Moore et al.; *supra*, ¶ 12.07[2.-1], at 12-52; *see generally Ohio Nat'l*

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[13] Compare with a motion to dismiss for failure to state a claim upon which relief can be granted under Rule 12(b)(6), in which allegations contained within the complaint are always taken as true and construed in a light most favorable to the non-moving party. *See, e.g., Hughes v. Rowe*, 449 U.S. 5, 9-10 (1980); *Abramson v. Brownstein*, 897 F.2d 389, 391 (9th Cir. 1990).

Life Ins. Co. v. United States, 922 F.2d 320, 325 (6th Cir. 1990) (draws clear distinction between facial and factual challenges to court's subject matter jurisdiction); *Mortensen v. First Fed. Savs. & Loan Ass'n*, 549 F.2d 884, 891-92 (3d Cir. 1977) (same). In establishing the predicate jurisdictional facts, a court is not restricted to the face of the pleadings, but may review evidence extrinsic to the pleadings, including affidavits and deposition testimony. *Land v. Dollar*, 330 U.S. 731, 735 n.4 (1947); *St. Clair v. City of Chico*, 880 F.2d 199, 201 (9th Cir.) (court did not err in considering materials outside pleadings in determining whether plaintiff 's claim was ripe), *cert. denied*, 493 U.S. 993 (1989); *Reynolds*, 846 F.2d at 747; *Indium Corp. of Am. v. Semi-Alloys Inc.*, 781 F.2d 879, 883-84, 228 USPQ 845, 848 (Fed. Cir. 1985), *cert. denied*, 479 U.S. 820 (1986).

In the present case, the government's Rule 12(b)(1) motion to dismiss clearly challenged Cedars' assertion that it had suffered any legally cognizable wrong:

> [A] Section 5908 determination does not have any immediate consequences nor does it cause any immediate change in the rights of interested parties.
>
> * * *
>
> [T]he Section 5908 determination did not and could not invade any legally protected right of the plaintiffs as to the invention. The effect of that determination [was] merely to notify [Cedars] of the agency's position . . . . [Energy's] position is not self-executing nor does it have any immediate legal effect.

The Rule 12 (b) (1) motion thus constitutes more than a mere facial challenge to Cedars' allegation of jurisdiction. It instead clearly disputes the factual basis for the allegations on which Cedars would establish jurisdiction over this case.

Cedars nevertheless argues that the government failed to present any evidence controverting its jurisdictional allegations contained within its pleadings. Cedars thereby displays its misunderstanding of its burden. The government's factual challenge to the court's jurisdiction placed the burden on Cedars to demonstrate facts sufficient to support its contention regarding the court's jurisdiction. Once challenged, allegations alone are insufficient to meet the complainant's burden. *Trentacosta*, 813 F.2d at 1559; *Thornhill Publishing*, 594 F.2d at 733. Thus, we must scrutinize the evidence submitted by Cedars as support for its otherwise naked jurisdictional allegations in order to determine whether this case is indeed ripe for adjudication.

Cedars relies, in main part, on an affidavit of Mr. Paul Yaeger, Cedars' Vice President, as support for its jurisdictional allegations. That affidavit first describes Yaeger's past success in licensing pending patent applications with third parties. It then continues:

> I am currently involved in third party negotiations relating to Cedars U.S. Patent Application Serial No. 559,430 which is the subject of the . . . December 10, 1991 Determination under § 5908; and . . . the § 5908 Determination has had a pronounced negative impact on such licensing negotiations which I believe will either greatly reduce the royalty income to the Medical Center or prevent the conclusion of any license agreement.

As the government perspicaciously contends, however, Yaeger's assertions relate solely to the effect of the Determination on "current[] . . . third party [licensing] negotiations relating to Cedars *U.S. Patent Application*." (emphasis added). The affidavit completely fails to discuss current licensing efforts with respect to Cedars' foreign patent rights. It asserts neither that such negotiations are ongoing or that, if ongoing, have been adversely affected by the Determination and are causing hardship to Cedars. Moreover, even if the Yaeger affidavit could be construed as referencing licensing of foreign patent rights, the conclusory statements do not provide the necessary factual basis to support jurisdiction. Facts must be set forth to demonstrate that the Determination directly and substantially interferes with Cedars' foreign licensing efforts. Conclusory statements, standing alone, are insufficient to carry Cedars' burden to prove hardship under the second prong of the *Abbott Laboratories* test.

The supporting affidavit of Cedars' representative, Mr. Coe Bloomberg, is likewise deficient. Though the affidavit establishes the fact that Cedars owns foreign patent rights, it fails to provide the evidence critical to its complaint's jurisdictional allegations. Thus, we find no evidence in the record to corroborate Cedars' assertions.

Furthermore, citing *Winter v. California Medical Review. Inc.*, 900 F.2d 1322 (9th Cir. 1990), the government argues that even if Cedars provided evidence to suggest that current licensing negotiations over its foreign patent rights have been adversely impacted by the Determination, such evidence could not overcome the ripeness hurdle in the Ninth Circuit, because it would evidence nothing more than "a possible financial loss." *Id.* at 1325. Cedars responds that the Determination's direct and immediate adverse effect on its day-to-day business affairs regarding its foreign patent rights

is sufficient to satisfy the hardship prong of *Abbott Laboratories*: Cedars alleges that it is now impossible to attract venture capital for its operation and the public is being harmed because of the impediment to disseminating the relevant technology.

The basis of the government's argument and the Ninth Circuit's law is found in the Supreme Court's observation that "a possible financial loss is not by itself a sufficient interest to sustain a judicial challenge to governmental action." *Abbott Labs.*, 387 U.S. at 153 (citing *Frothingham v. Mellon*, 262 U.S. 447, 487-88 (1923)). Though we need not reach this issue to resolve the present appeal, we question the government's casual classification of damage to a patentee's intellectual property rights as "mere financial loss." *See Patlex Corp.*, 758 F.2d at 599, 225 USPQ at 246.

Thus, with regard to Cedars' foreign patent rights, we conclude that any error committed by the district court in its analysis of the first prong of *Abbott Laboratories* is harmless considering the fact that Cedars failed to demonstrate hardship sufficient to satisfy the second prong of the ripeness analysis.[14]

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[14] This case is distinguishable from *Abbott Laboratories*, in which uncontested allegations, 387 U.S. at 152, established that the new drug-labelling regulations in question had an immediate impact on the complainants: They would have either had to make an immediate, substantial monetary investment to comply with the new requirements, or risked serious civil and criminal penalties for failing to do so. In the present case, however, on the record before this court, Cedars has not demonstrated any immediate harm with respect to its foreign patent rights.

V

Because of the constitutional limitations on jurisdiction of the federal courts, the district court's dismissal of the action as unripe is

AFFIRMED.

APPENDIX B

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

FILED

MAY 19 1992

CLERK,
U.S. DISTRICT COURT
CENTRAL DISTRICT
OF CALIFORNIA

CEDARS-SINAI MEDICAL CENTER,
a not-for-profit California corporation, et al.,

Plaintiffs,

v.

JAMES D. WATKINS,
Secretary of the United States Department of Energy,

Defendant.

Case No. CV 92-0154 JGD
Entered in Civil Docket MAY 26 1992

ORDER DISMISSING ACTION WITHOUT PREJUDICE

On May 18, 1992, the following motions came before the Court for hearing: (1) defendant's Motion to Dismiss and Motion for Stay of Proceedings; (2) plaintiffs' Motion for Judgment; (3) plaintiffs' Motion for Summary Judgment Re Inapplicability of 42 U.S.C. § 5908; and (4) plaintiffs'

Motion for Summary Judgment Re Unconstitutional Acts of Richard E. Constant, Esq. The Court has reviewed and considered the parties' papers and the oral arguments of counsel. Based upon this review, the Court HEREBY GRANTS defendant's motion to dismiss because this action is not ripe for judicial adjudication. Since the Court lacks jurisdiction, it will not rule on the other motions.

FACTUAL BACKGROUND

Plaintiff Cedars-Sinai ("Cedars") is a non profit corporation that operates a hospital. Plaintiffs Warren S. Grundfest, M.D., James S. Forrester, M.D. and Frank Litvack, M.D. are all medical doctors who specialize in cardiology at Cedars. Defendant James D. Watkins is the Secretary of the United States Department of Energy.

In June 1983, Dr. Grundfest approached the Argonne National Laboratory and obtained permission to conduct certain experiments in the area of laser angioplasty. Dr. Dieter M. Gruen, a close relative who had arranged Dr. Grundfest's visit, participated in the experiments.

On December 8, 1983, Dr. Grundfest filed an application for a United States Patent (S.N. 559,430) entitled "Method of Medical Treatment Using an Excimer Laser on Organic Tissue."

On January 9, 1984, Dr. Gruen filed an initial patent application which was superceded by a later application filed on February 19, 1995 [sic] entitled "Excimer Laser Phototherapy for the Dissolution of Abnormal Growth." *See* United States Patent No. 4,686,979 (attached as Exhibit A to Government's Motion to Dismiss Plaintiffs' Complaint). On August 18, 1987, that application was granted and the United States was named as assignee.

Another patent application covering a similar invention was filed by an individual named Linsker.

There is now pending an interference action (Interference No. 102,459) before the Board of Patent Appeals and Interferences (the "Board"). The subject matter of the interference action is who among Grundfest, Gruen and Linsker was the first to invent the surgical technique known as laser angioplasty.

On December 10, 1991, Richard E. Constant, who is the Assistant General Counsel for intellectual property within the Department of Energy, served upon Cedars a docume... entitled "Determination Under 42 U.S.C. § 5908" (the "DOE Determination"). The DOE Determination stated that if Dr. Grundfest's group invented the surgical technique, they did so with the contribution of the government or the use of government facilities. Thus, the DOE Determination concluded that the invention was made in the manner provided by 42 U.S.C. § 5908 and, therefore, belonged to the United States. *See* Complaint, Exhibit B.

By this present action, Cedars argues that the DOE Determination was procedurally defective on several grounds, including: Cedars had no notice that the Department of Energy intended to make such a determination, the DOE Determination was made without a hearing and there was no opportunity for Cedars to present or challenge relevant facts. In addition, Cedars challenges the DOE Determination on the basis that there were no regulations that governed the making of such a determination, and that, in any event, Mr. Constant was not a neutral decision maker because his office represents Dr. Gruen's group in the pending interference action.

Cedars also contends that the government is guilty of laches because the government did not assert any claims to the fruits of the June 1983 experiment until many years later. In the interim, Cedars claims that they expended significant

resources to further develop laser angioplasty. Finally, Cedars claims that 42 U.S.C. § 5908 is not applicable to this situation because another statute, 35 U.S.C. §§ 200, et seq., takes precedence since there is no "funding agreement" in this case.

Cedars' complaint alleges two causes of action: (1) to set aside the DOE Determination because it violates procedural due process; and (2) for declaratory judgment on issues relating to the applicability of 42 U.S.C. § 5908 and/or 35 U.S.C. §§ 200, et seq., the validity of the DOE Determination, and whether the government is barred by laches.

Various motions are now pending before the Court. Plaintiffs have filed a Motion for Judgment, a Motion for Summary Judgment Re Inapplicability of 42 U.S.C. § 5908, and a Motion for Summary Judgment Re Unconstitutional Acts of Richard E. Constant, Esq. These various motions in someway challenge the propriety of the DOE Determination and conclude that it was constitutionally infirm on procedural due process grounds.

Defendant has filed a Motion to Dismiss and a Motion for Stay of Proceedings. Because the Court finds that this controversy is not ripe for judicial adjudication and should therefore be dismissed, the Court will begin its discussion with an analysis of defendant's motion to dismiss.

DISCUSSION

The defendant make two arguments for dismissal. First, defendant argues that this Court lacks subject matter jurisdiction, and thus seeks to dismiss pursuant to Fed. R. Civ. P. 12(b)(1). Second, defendant argues that plaintiffs' complaint fails to state a claim upon which relief may be granted, and thus defendant seeks to dismiss pursuant to Rule

12(b)(6). Since defendant answered plaintiffs' complaint on April 6, 1992, defendant's Rule 12(b)(6) is untimely because such a motion must be made prior to filing an answer. Therefore, the Court need only consider defendant's Rule 12(b)(1) motion which challenges the Court's subject matter jurisdiction, and thus encompasses the doctrine of ripeness.

The ripeness doctrine prevents premature adjudication. It is aimed at cases that do not yet have a concrete impact on the parties. *See Thomas v. Union Carbide Aqricultural Prod. Co.*, 473 U.S. 568, 580 (1985). Ripeness requires that a dispute have progressed beyond the point where a legal question is merely hypothetical.

Ripeness is a part of the case or controversy limitation of Article III. If a question is too hypothetical or abstract at the time it is posed, it is beyond the constitutional competence of an Article III court.

"Because ripeness is 'peculiarly a question of timing,' we look at the facts as they exist today in evaluating whether the controversy before us is sufficiently concrete to warrant our intervention." *Assiniboine and Sioux Tribes v. Bd. of Oil and Gas*, 792 F.2d 782, 788 (9th Cir. 1986).

The most widely accepted doctrinal formulation for ripeness was explained by the Supreme Court in *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148-49 (1966):

> [the] basic rationale [of the ripeness doctrine] is to prevent courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties. The problem is best seen

> in a twofold aspect, requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.

Under the two-pronged inquiry of *Abbott Laboratories* the case is nonjusticiable. First, the issues are not fit for judicial decision since the interference action is still pending and the Board has not yet issued an opinion. The Board has exclusive jurisdiction to hear and determine issues raised in an interference action. 35 U.S.C. § 135(a); *Deltec. Inc. v. Laster*, 326 F.2d 443, 444 (6th Cir. 1964). In rendering a final decision in the interference proceeding, the Board may consider any properly raised issue including the priority of the invention, the patentability of the invention and any other matter necessary to resolve the interference. 37 C.F.R. § 1.655(a).

A party to an interference action who wishes to challenge the Board's decision may file an appeal to the United States Court of Appeals for the Federal Circuit pursuant to 35 U.S.C. § 141 or the party may file a civil action in a federal district court pursuant to 35 U.S.C. § 146. Since there has been no decision by the Board, plaintiff's filing of the instant complaint is premature. It is possible that the Board could decide that the patent belongs to the Gruen group, which currently holds the patent. Alternatively, Linsker may be awarded the patent. If the Board were to rule in either of these two ways, the DOE Determination would be of absolutely no consequence because it only says that in the event the Board awards the patent to the Grundfest group, the United States would still own the patent by virtue of § 5908.

Second, and more importantly, there is no significant hardship in withholding judicial decision. As discussed above, the Board may consider the propriety of the DOE

Determination in connection with making its ultimate decision. 37 C.F.R. § 1.655(a). Moreover, plaintiffs have two avenues to challenge the Board's ultimate decision. 35 U.S.C. §§ 161, 146. Until such time as the Board enters its decision, this controversy lacks the concrete presentation of issues required by Article III. Thus, this Court lacks jurisdiction to adjudicate plaintiffs' complaint.

Plaintiffs argue that this case is ripe for adjudication because the DOE Determination has had an immediate impact on them. They claim the DOE Determination affects their ability to license patents that they hold in other countries. Essentially, plaintiffs contend that they have suffered immediate injury from the DOE Determination because it clouds title to their foreign patents, impairing their ability to license those patents.

Nevertheless, plaintiffs' arguments fail to vest this Court with subject matter jurisdiction. Under the two-pronged analysis of *Abbott Laboratories*, this case is premature. First, the issues are not fit for adjudication since the Board has not ruled on the interference action. Second, there is no significant hardship in withholding judicial decision. Unlike *Abbott Laboratories*, there is no risk of criminal penalties here. Plaintiffs will remain free to challenge the Board's decision.

CONCLUSION

For the reasons discussed above, plaintiffs' complaint is not ripe for judicial adjudication. Therefore, the Court HEREBY DISMISSES WITHOUT PREJUDICE plaintiffs' complaint for lack of subject matter jurisdiction.

IT IS SO ORDERED.

Dated: May 19, 1992

/s/ John G. Davies
JOHN G. DAVIES
United States District Judge

APPENDIX C

[EXCERPTED PAGES]

Paper No. 65

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: BOX INTERFERENCE
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Telephone: (703) 557-4007
Facsimile: (703) 557-8642

Interference No. 102,459

Gruen et al.

v.

Linsker

v.

Grundfest et al.

DECISION ON PRELIMINARY MOTIONS

****

[PAGES 2-38 OMITTED]

* * * *

Motion (7) by Gruen et al. under 37 CFR on 1.635 to award ownership of any patent issuing on Grundfest et al. application to DOE - dismissed

In this motion, Gruen et al., whose application is assigned to DOE, request that any patent which issues on the involved Grundfest et al. application be issued to DOE on behalf of the United States under 42 U.S.C. § 5908. A testimony period is also requested.

By way of background, on December 1991, which is subsequent to declaration of this interference, DOE issued a determination (paper No. 52, Ex. B) that "the activities of Grundfest, Forrester, and Litvak in relation to the invention were carried out with a contribution by the Government of the use of Government facilities, equipment, materials and allocated funds" and that the invention was therefore made in the manner specified by 42 U.S.C. 5908, which provides that title to an invention made under these circumstances shall vest in the United States. On January 9, 1992, Grundfest, Forrester and Litvak and Cedars-Sinai Medical Center, the assignee of their involved application, filed a complaint in the United States District Court for the Central District of California seeking to set aside the DOE determination. On May 19, 1992, the court dismissed the complaint without prejudice on the ground that the ownership controversy is not yet ripe for judicial review, since the board might award the subject matter of the interference to Gruen et al. or to Linsker, in which case ownership of the involved Grundfest et al. application would be of no consequence.

Grundfest et al. oppose the motion on a number of grounds. The first is that the motion fails to include the certification of consultation with the opposing parties and an indication of whether the opposing parties intend to oppose

the motion, as required by 37 CFR 1.637(b). Although this rule is incorrectly identified as 37 CFR 1.636(b) at page 2 of the opposition, the correct rule number appears at pages i, 4 and 6, the text of the correct rule is reproduced at page 4, and the arguments make it clear which rule is at issue. Under these circumstances, there is no merit to Gruen et al.'s argument (reply, p. 1) that "37 CFR 1.636(b) does not apply to Party Gruen's motion." The motion is therefore dismissed for failing to comply with the requirements of 37 CFR 1.637(b).

The motion is also dismissed on the alternative ground that it is not a miscellaneous motion of the type authorized by 37 CFR 1.635. *See Theeuwes v. Bogentoft*, 2 USPQ2d 1378, 1379 (Comm'r 1986); *Gerk v. Cottringer*, 17 USPQ2d 1615, 1616 (BPAI 1990).

Furthermore, an interference proceeding is not the proper forum for ascertaining the ownership of an invention. *See* 1 Rivise and Caesar, *Interference Law and Practice* § 5 (1940). Although 37 CFR 1.602(b) requires parties involved in an interference to identify any and all right, title and interest in their involved patents and applications, if not already set forth in the notice declaring the interference, the board is not authorized to decide which of two competing claimants is entitled to ownership of an involved application or patent. Instead, the board is authorized by 35 U.S.C. § 7 to decide only patentability and priority issues, neither of which includes the issue of ownership. Likewise, although the PTO records assignments of applications and patents (35 U.S.C. § 261; 37 CFR 1.331; MPEP § 301), it does not decide ownership disputes.

In view off the dismissal of the motion, the accompanying request to take testimony is denied.

****

[PAGES 42 - 49 OMITTED]

Requests for Reconsideration

Since this decision does not include an order to show cause under 37 CFR 1.640(d), requests for reconsideration of the decision may be filed in accordance with 37 CFR 1.640(c). However, the time for filing such a request is hereby set at 21 days instead of the 14 days provided in the rule. In addition, each party is hereby authorized to file an opposition to each such a request within 10 days of the date of service of the request. No reply to an opposition is authorized.

The parties are reminded to include the "BOX INTERFERENCE" notation on the outside of all envelopes containing interference papers.

Preliminary Statements

The preliminary statements will remain sealed until the time for requesting reconsideration has passed without any such request being filed or, if a request is filed, until a decision on reconsideration is rendered. If the substitution of new count 3 for count 2 is not set aside on reconsideration, the parties will be given an opportunity to file new preliminary statements, if they desire.

/s/ John C. Martin

John C. Martin
Examiner-in-Chief
703-557-4084

APPENDIX D

[EXCERPTED PAGES]

Paper No. 79
JCM/caw

UNITED STATES PATENT
AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Patent Interference No. 102,459

Gruen et al. v. Linsker v. Grundfest et al.

RECONSIDERATION

Calvert, Vice Chairman, Pate, and Martin,
Examiners-in-Chief.
Martin, Examiner-in-Chief.

* * * *

[PAGES 2-6 OMITTED]

* * * *

Gruen et al. Motion 7

In this motion under 37 CFR 1.635, Gruen seek [sic] to have any patent that issues on the involved Grundfest et al.

application issued to DOE on behalf of the United States pursuant to 42 U.S.C. § 5908. Recognizing that 37 CFR Subpart E (Interferences) does not specify a procedure applicable to the motion, the motion requested the Board to follow a procedure similar to that followed under Section 152 of the Atomic Energy Act of 1954 (42 U.S.C. §2182), which authorizes this Board to decide ownership of nuclear related inventions. This motion was dismissed by the EIC on three grounds: (1) assuming it is a proper 37 CFR 1.635 motion, it lacks the certificate of consultation required by 37 CFR 1.637(b) for all 37 CFR 1.635 motions; (2) it is not a miscellaneous motion of the type authorized by 37 CFR 1.635; and (3) the Board lacks the authority to decide the ownership question raised in the motion.

As for ground (1), Gruen et al. contend that under the circumstances a conference would have been futile and that to apply 37 CFR 1.637(b) to the motion therefore would have been "an unthinking, mechanical application of the rule without regard to its stated purpose," which is to make "an effort in good faith to resolve by agreement the issues raised by the motion." However, the Board is without authority to waive the requirements of the rules, *Miller v. Chester*, 13 USPQ2d 1387, 1388 (BPAI 1989), and 37 CFR 1.637(b) requires a conference regardless of the likelihood of success.

In response to ground (2), which is that the motion is not a miscellaneous motion of the type authorized by 37 CFR 1.635, Gruen et al. argue that the EIC overlooked the fact that motion is grounded in part on 42 U.S.C. § 5908. However, the fact that the EIC in discussing this motion mentions this statute at pages 39 and 40 demonstrates that he did not overlook or misapprehend this fact.

We are also not persuaded that the EIC overlooked or misapprehended any point in holding that this Board lacks the authority to decide the particular ownership issue raised in the

motion. As the EIC correctly noted in his decision, 35 U.S.C. § 7 confers no such authority on the Board. Nor is the authority to decide this particular ownership issue conferred on this Board by 42 U.S.C. § 2182, which concerns only nuclear related inventions.

To the extent the request for reconsideration also relies on 42 U.S.C. § 2457 (the Space Act), it is entitled to no consideration, since this statute was not cited in the motion. Nevertheless, we note that this statute, too, fails to authorize this Board to consider the ownership question raised in the motion. In the absence of specific statutory authority, this Board cannot and will not decide this ownership question.

* * * *

[PAGES 9-10 OMITTED]

* * * *

Remand to EIC

This interference is remanded to the EIC for further proceedings consistent with this decision.

/s/ Ian A. Calvert	)	
Ian A. Calvert	)	
Vice Chairman	)	
	)	
/s/ William F. Pate	)	BOARD OF PATENT
William F. Pate, III	)	APPEALS AND
Examiner-in-Chief	)	INTERFERENCES
	)	
/s/ John C. Martin	)	
John C. Martin	)	
Examiner-in-Chief)	)	

APPENDIX E

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE COMMISSIONER OF PATENTS AND TRADEMARKS

DIETER M. GRUEN, CHARLES E. YOUNG, and MICHAEL J. PELLIN,	)	
v.	)	
RALPH LINSKER,	)	Interference No. 102,459
v.	)	
WARREN S. GRUNDFEST, JAMES S. FORRESTER, and FRANK LITVACK.	)	

DECISION ON PETITION

* * * *

[PAGES 2-4 OMITTED]

* * * *

B. Gruen's Requests to the Board

Before the Board of Patent Appeals and Interferences, Gruen has sought in various ways to have the Board consider, apparently as part of the interference, the question of whether

the United States is the owner of the Grundfest application, presumably based on the "determination" of December 10, 1991. Gruen claims that the Board has authority to consider the ownership issue through either a preliminary motion under 37 CFR § 1.633 or a miscellaneous motion under 37 CFR § 1.635. The Board concluded that it lacks authority to consider the ownership question.

C. Gruen's Petition

The rules authorize a petition to the Commissioner in an interference only under three circumstances.

(1) A question may be certified by the Board. 37 CFR § 1.644 (a)(1). There has been no certification by the Board in this case.

(2) A petition may seek to invoke the supervisory authority of the Commissioner. 37 CFR § 1.644(a)(2). However, a petition seeking to invoke supervisory authority cannot be filed until after a final judgment is entered by the Board. 37 CFR § 1.644(b). The Board has not entered a final judgment in this interference.

(3) A petition may seek waiver of a rule. 37 CFR § 1.644(a)(3). A petition to waive a rule may be filed at any time. However, a petition to waive a rule cannot be filed as a disguised request seeking to invoke supervisory authority. *See e.g., Hasegawa v. Kuda,* 1985 Comm'r Pat. LEXIS 21 (Comm'r Pat. 1985) (*see* Attachment No. 6), which notes:

> Accordingly, it will not be the practice of the Patent and Trademark Office under the new rules to consider, under the guise of 37 CFR § 1.183, routine petitions which seek to invoke supervisory authority and thereby defeat the very purpose of new Rule 644(a).

Moreover, it should not be expected that the rules will be waived on a routine basis. *Myers v. Feigelman*, 455 F.2d 596, 601, 17 USPQ 580, 584 (CCPA 1972) (waiver of rules on routine basis would defeat the purpose of the rules and substantially confuse interference practice).

It appears that Gruen is petitioning for waiver of "any" regulation which may stand in the way of the Board considering on the merits the question of ownership of the Grundfest application. Although relief was requested under 37 CFR § 1.183, the petition is vague as to the precise rule to be waived, why any waiver would be in the interest of justice, or why any extraordinary circumstance is presented.

There can be no extraordinary circumstance in this case. The Board is an administrative body having limited statutory jurisdiction. No statute authorizes the Board to make ownership determinations under 42 U.S.C. § 5908. The Board's statutory jurisdiction in interference cases is set out in 35 U.S.C. § 135(a). The Board has authority to decide priority and patentability. It does not have statutory authority to decide ownership in an interference. *Beech Aircraft Corp. v. Edo Corp.*, Nos. 92-1097, 92-1098, 92-1108, 92-1109, slip. op. at 26-27 (Fed. Cir. April 22, 1993).

The Board has limited statutory authority to decide "title" disputes under 42 U.S.C. § 2182 and 42 U.S.C. § 2457. Both § 2182 and § 2457 give the Board subject matter jurisdiction to consider whether patents should issue to the United States *vis-a-vis* an applicant. But, both sections authorize only the applicant, not the United States, to ask for a hearing before the Board. Section 5908, upon which Gruen relies, does not expressly authorize the Board to consider the question of title at the request of the United States. Since Congress used express statutory language in § 2182 and § 2457 to give the Board subject matter jurisdiction over certain title disputes, its having not done so in § 5908 is a

compelling inference that had Congress intended for the Board to resolve § 5908 title disputes, it would have so provided. *Compare Klein v. Commissioner*, 474 F.2d 821, 825, 177 USPQ 1, 4 (4th Cir. 1973).

The sole issue which seems to be raised by the petition is whether the Board erred in entering an interlocutory decision holding that it lacked subject matter jurisdiction to determine whether the United States or Grundfest is the owner of the Grundfest application involved in the interference. Review of the Board's interlocutory order can be had along with review of any final order entered in this interference.

For the reasons given above, the narrow issue presented by the petition must be resolved against Gruen and the petition must be *denied.*

Order

Upon consideration of Gruen's PETITION (Paper No. 94); MEMORANDUM OF LAW IN SUPPORT OF PETITION TO COMMISSIONER (Paper No. 93); and ADDENDUM TO MEMORANDUM OF LAW IN SUPPORT OF PETITION (Paper No. 95), and Grundfest's OPPOSITION TO JUNIOR PARTY GRUEN'S PETITION (Paper No. 97), it is

ORDERED that the petition is *denied*, and it is

FURTHER ORDERED that the interference is returned to the Board for such further action as may be appropriate.

May 24, 1993

/s/ Michael K. Kirk
MICHAEL K. KIRK
Acting Commissioner of
Patents and Trademarks

APPENDIX F

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

LYON & LYON
A Partnership Including
COE A. BLOOMBERG
A Professional Corporation
JERROLD B. REILLY
LOIS KWASIGROCH
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FILED
CLERK,
U.S. DISTRICT COURT

JAN 9 1992

CENTRAL DISTRICT
OF CALIFORNIA

Attorneys for Plaintiffs
CEDARS-SINAI MEDICAL CENTER, et al.

CEDARS-SINAI MEDICAL CENTER, a not-for-profit California Corporation, WARREN S. GRUNDFEST, M.D., JAMES S. FORRESTER, M.D., and FRANK LITVACK, M.D.,

Plaintiffs,

v.

JAMES D. WATKINS,
Secretary, United States Department of Energy,

Defendant.

Case No. 92-0154 JGD (EX)

COMPLAINT TO SET ASIDE UNLAWFUL AGENCY ACTION AND FOR DECLARATORY AND INJUNCTIVE RELIEF; DEMAND FOR JURY TRIAL

Plaintiffs, as and for their complaint against defendant, allege as follows:

THE PARTIES

1. Plaintiff Cedars-Sinai Medical Center ("Cedars") is, and at all times material has been, a not-for-profit corporation organized and existing under the laws of the state of California and having its offices and facilities within the county of Los Angeles, California, with a principal business address at 8700 Beverly Boulevard, Los Angeles, California. Cedars was founded in 1902 and is, and at all times material has been, engaged in the operation of a hospital and related facilities at and through which patient care, medical research, and medical teaching activities are conducted. At present, Cedars has a 2,200 member medical staff. The Cedars facilities are located on more than 24 acres of land and include a 1,200 bed hospital for patient care.

2. Plaintiff Warren S. Grundfest, M.D. ("Dr. Grundfest") is a resident of the County of Los Angeles, California. Dr. Grundfest is, and at all times material has been, a medical doctor, a specialist in cardiovascular surgery, and a participant in the cardiology and vascular surgery research group at Cedars. Dr. Grundfest joined Cedars as a General Surgery Resident in 1982 and became Chief General Surgery Resident in 1984. From 1987 to 1990, Dr. Grundfest was the Assistant Director of Surgery and Director of Laser Surgery and Surgical Research at Cedars. In 1990, Dr. Grundfest was appointed to head the Department of Laser Research and Technology Development at Cedars. In 1991, Dr. Grundfest was awarded the Dorothy and E. Philip Lyon chair in Laser Research. Additionally, Dr. Grundfest is an

Assistant Clinical Professor of Surgery at the UCLA School of Medicine.

3. Plaintiff James S. Forrester, M.D. ("Dr. Forrester") is a resident of the County of Los Angeles, California. Dr. Forrester is, and at all times material has been, a medical doctor, a specialist in cardiovascular surgery, and the Director of the Specialized Center for Research in Ischemic Heart Disease at Cedars.

4. Plaintiff Frank Litvack, M.D. ("Dr. Litvack") is a resident of the County of Los Angeles, California. Dr. Litvack is, and at all times material has been, a medical doctor and a specialist in cardiology. Dr. Litvack is currently co-director of the Cardiac Catheterization Laboratory at Cedars. In January of 1991, Drs. Grundfest, Forrester, and Litvack were recipients of the Goldman Medical Excellence Award. This award "recognizes outstanding contribution in the field of medical optics" and was presented "for innovative work in the conception, development, and clinical testing for an optimized laser angioplasty system, the first coronary laser system to obtain FDA panel recommendation for clinical use."

5. Upon information and belief, defendant, James D. Watkins (hereinafter sometimes called "the Secretary"), holds the office of Secretary of Energy, and in that capacity is the head of the United States Department of Energy ("DOE"), which has its headquarters at 1000 Independence Avenue, S.W., Washington, D.C. 20585, within the District of Columbia, where, upon information and belief, Mr. Watkins maintains the principal office from which he conducts his affairs as Secretary of Energy.

JURISDICTION AND VENUE

6. This Court has jurisdiction of the First Cause of Action set forth below pursuant to the Federal Administrative Procedure Act (*See* 5 U.S.C. §§702-706) and pursuant to 28 U.S.C. §1331; and this Court has jurisdiction of the Second Cause of Action set forth below pursuant to 28 U.S.C. §2201 and 28 USC §1331.

7. Venue properly lies in this District pursuant to 28 U.S.C. §1391(e)(3), because the defendant is an officer of the United States acting in his official capacity, all plaintiffs reside in this District, and no real property is involved in this action.

BACKGROUND
(The Invention and the Patent Office Interference Proceeding)

8. On December 8, 1983, Dr. Grundfest filed an application for a United States Patent (S.N. 559,430), entitled "Method of Medical Treatment using an Excimer Laser on Organic Tissue," which application is directed to, among other things, the *in vivo* ablative reduction of a lesion on a wall of a blood carrying lumen. Subsequent patent applications were later filed adding Drs. Forrester and Litvack as inventors, hereafter referred to as "Grundfest, et al."

9. Cedars is the owner, by assignment, of United States Patent Application Serial No. 559,430 and its later filed patent application progeny (hereinafter "the Grundfest et al. application").

10. Upon information and belief, DOE is the purported owner of United States Patent No. 4,686,979 entitled "Excimer Laser Phototherapy For the Dissolution of Abnormal Growth" (hereinafter "the Gruen patent"), issued on August 18, 1987 to Dieter M. Gruen, Charles E. Young, and Michael J. Pellin, hereafter "Gruen et al.," who, upon information and belief, are, and at all times material have been, employed by the Argonne National Laboratory which is operated under contract for DOE by the University of Chicago. The Gruen patent is directed to the *in vivo* ablative reduction of a lesion on a wall of a blood carrying lumen.

11. The Gruen patent and the Grundfest et al. application are involved, together with the application of one Linsker, in Interference No. 102,459, now pending before the Board of Patent Appeals and Interferences within the United States Patent Office, which proceeding aims to determine which party, among the three, was first to invent the subject matter in question. The subject matter involved in this Interference proceeding, hereafter referred to as "the Invention," has been defined by the Patent Office as follows:

> "A method of *in vivo* ablative reduction of a lesion or a wall of a blood carrying lumen comprising:
>
> delivering laser energy to said lesion, said laser energy having a wavelength in the range of 210-400 nm and ablatively reducing at least some of the lesion *in vivo* with little or no thermal damage to said lumen."

The Patent Office has designated Grundfest, et al. the Senior Party, because Dr. Grundfest filed his patent application earlier than either Linsker or Gruen, et al.

12. The Invention relates to a surgical technique known as laser angioplasty. That technique is described, and some of its advantages discussed, in an article in the "Science Times" section of the *New York Times* dated January 29, 1985, a true copy of which article is attached hereto as EXHIBIT "A" and incorporated herein by reference.

13. The Invention is an important breakthrough in cardiovascular surgery. It has significant implications for the public health and welfare, inasmuch as heart disease is the leading cause of death in the United States. There are currently some five million cases of coronary artery disease in the United States alone, with that number increasing by an estimated 800,000 cases in this country annually. Coronary bypass surgery, a traditional treatment whereby replacement arteries are surgically substituted for coronary arteries blocked by atherosclerotic plaque, is highly invasive, requires relatively long recovery times, is highly risky and is very expensive. In 1981 it was a $4 billion/year industry in the United States, and it is even more expensive now that costs have risen to an average of $20,000 to $40,000 per procedure and numbers of patients have risen as well. Balloon angioplasty (involving the introduction into the partially-blocked blood vessel of a balloon and inflation of the balloon to crush the obstruction into the vessel wall) is somewhat less expensive than coronary bypass surgery but is often ultimately unsuccessful. Some 1% of patients die during the procedure; 5% have complications requiring emergency heart surgery; and 40% eventually experience re-obstruction of the vessel at the original site, so that repeat procedures are frequently

necessary. Besides, balloon angioplasty is largely unsuccessful against large or highly calcified plaque deposits and there are certain limits to the amount of plaque that may be opened by balloon angioplasty. The Invention, affording a means of harmlessly vaporizing atherosclerotic plaque without thermal damage to the artery itself, offers the prospect of cheaper, safer, less invasive surgery with a lower occurrence of reobstruction and relatively short recovery times; and this promises significantly better medical results with significant lowering of health-care costs.

14. By reason of the foregoing, the Invention is an extremely valuable intellectual property and the right to exploit and practice the Invention is an extremely valuable right.

(The DOE Determination and its Defects)

15. On December 10, 1991, and subsequent to the commencement of Interference No. 102,459, Richard E. Constant, who upon information and belief is the Assistant General Counsel for intellectual property within DOE, issued and served upon counsel for Cedars a two-page document styled "Determination Under 42 U.S.C. 5908," a true and correct copy of which is attached hereto as EXHIBIT "B" (hereinafter the "DOE Determination"). The DOE Determination, after a recitation of purported facts, purports to determine

> "that the activities of Grundfest, Forrester, and Litvack in relation to the invention were carried out with a contribution by the Government of the use of Government facilities, equipment, materials, and allocated

> funds and that the invention is related to the arrangement or understanding under which the participants in the research operated and the work they performed and therefore that the invention, if it was made by Grundfest, Forrester, and Litvack was made in the manner specified in 42 U.S.C. 5908."

16. The DOE Determination, if allowed to stand, will constitute a governmental taking from plaintiffs of valuable rights and property, in that the DOE Determination provides that title to the Invention "shall vest in the United States" if the Secretary makes certain determinations, which the DOE Determination then purports to make. Upon information and belief, the DOE Determination will delay the availability of laser angioplasty to the public and medical community; because much of the present coronary bypass surgery and balloon angioplasty is performed on patients covered by Medicare, such delay in the employment of laser angioplasty will cost the Government hundreds of millions of dollars in Medicare payment which could othervise he reduced by wide application of laser angioplasty.

17. The making of the DOE Determination was not preceded by the giving of any notice to any of the plaintiffs or their counsel that the DOE intended to take action to determine the status of the invention under 42 USC § 5908.

18. The DOE Determination was made entirely *ex parte*, without any hearing and without affording any of the plaintiffs, or their counsel, any opportunity to present evidence or argument.

19. Upon information and belief, the DOE Determination was made without the taking of any sworn testimony of any witness.

20. Upon information and belief, the DOE Determination was made without the making of any record (beyond the recitation of purported facts in the Determination itself) of the evidence, if any, which DOE relied upon in making the determination.

21. The DOE Determination was made without affording any of the plaintiffs, or their counsel, any opportunity to confront or cross-examine any adverse witness.

22. The DOE Determination was made without affording any of the plaintiffs, or their counsel, any opportunity to take discovery as to any of the purported facts upon which the DOE Determination purports to be based.

23. The DOE Determination was made without first affording any of the plaintiffs, or their counsel, any opportunity to impeach, rebut or othervise traverse any purported item of evidence upon which the Determination purports to be based.

24. The DOE Determination was made in reliance upon purported evidence which would not have been admissible over timely objection had it been introduced during an adversary hearing under the Federal Rules of Evidence, or under any other evidence rules affording a level of procedural fairness sufficient to comport with due process.

25. Upon information and belief, the source and grounds of which are a conversation between counsel for DOE and counsel for plaintiffs, no duly promulgated and published regulations exist which governed the making of the DOE Determination or which govern any reconsideration or appeal therefrom; and DOE, in making the Determination and in purporting to impose a 30-day time limit and certain content requirements on any request for reconsideration, acted on a purely *ad-hoc* basis. As explained more fully in paragraph 27, the DOE Determination was filed by counsel for Gruen et al. in the motion proceedings of Interference No. 102,459. The DOE motion requested that the Board of Interference enter an Order that any patent granted to Grundfest et al. be issued to the DOE under 42 USC 5908 and stated, in part:

> "To the extent that 37 C.F.R. subpart E does not specify procedures applicable to this motion, the Board should accept this motion or direct the parties as to procedures necessary to implement the statute."

26. Richard E. Constant, who signed the DOE Determination, was, upon information and belief, not lawfully and properly appointed and delegated to act for the Secretary in the making of determinations under 42 USC § 5908 generally, or in the making of the DOE Determination here at issue in particular.

27. Upon information and belief, Richard E. Constant, who made and signed the DOE Determination, was not and is not an independent, neutral and impartial decision-maker, for reasons including the following:

(a) Mr. Constant is, and at all times material was, the person in charge of the office having direct responsibility for prosecuting patents on behalf of DOE; and his office prosecuted the application which issued into the Gruen patent, which application failed to name Grundfest, et al. as inventor.

(b) Mr. Constant's office is now representing Gruen, et al. in Interference No. 102,459, in which proceeding DOE, as owner of the Gruen patent and real party in interest, is adverse to Grundfest, et al.

(c) By a preliminary motion which Grundfest et al. have filed and which is now pending in Interference No. 102,459, it is alleged that Gruen et al. are guilty of inequitable conduct in that they failed, with intent to deceive the Patent Office, to disclose Plaintiffs' role in the making of the invention, and failed to name Grundfest, et al. as inventor on the Gruen et al. application.

(d) Grundfest et al. are seeking, in connection with said preliminary motion, to take testimony of personnel within Mr. Constant's office to ascertain, among other things, what if anything was told to, or inquired about by, the attorneys who prosecuted the Gruen, et al. application regarding Plaintiffs' role in making the invention therein claimed.

(e) Because the circumstances alleged in Grundfest et al.'s preliminary motion suggest, and the testimony sought by that motion may reveal, that personnel within Mr. Constant's office were guilty of negligence or other malfeasance in the matter of investigating and/or deciding whether to disclose Grundfest et al.'s role with respect to the invention of the subject matter of the Gruen et al. application, Mr. Constant possesses a plain motive to discourage inquiry into the matter -- a result which could be accomplished if it were determined that DOE owns the Grundfest et al. application and any patent to issue thereon, so that plaintiffs would no longer have a motive to investigate possible malfeasance by Mr. Constant's office.

(f) Upon information and belief, Mr. Constant deliberately timed the DOE Determination with a view to improving DOE's position as a litigant in Interference No. 102,459. Mr. Constant's office notified plaintiffs and their counsel of the DOE Determination by attaching a copy of it to Gruen, et al.'s motion papers, approximately eight and one-half years after the occurrence of the mid-1983 events which the Determination purports to rely upon.

(Laches, Estoppel & Waiver)

28. Upon information and belief, the source and ground of which is a declaration of Dr. Fred A. Cafasso of Argonne National Laboratory ("Argonne") which has been filed in Interference No. 102,459, it was Dr. Cafasso who decided to allow Dr. Grundfest to be admitted to Argonne's laboratory for the June 25, 1983 experiments which are described (albeit inaccurately) in the DOE Determination; and Dr. Cafasso granted that permission for the reasons that the proposed experiments did not compete with any work that Argonne's Chemistry Department was then doing; that use of the laboratory on a Saturday afternoon would not disrupt the normal laboratory activities; and that it was the policy of Argonne to encourage "nominal collegial interchanges." Dr. Grundfest et al. had worked in the area of cardiovascular surgery for several years prior to 1983, with special emphasis on laser angioplasty research. Dr. Grundfest approached Argonne Laboratories with as intent to carry out specific experiments in the area of laser angioplasty. Dr. Grundfest was subsequently invited to Argonne in the spirit of scientific goodwill and "nominal collegial interchange." Dr. Grundfest's visit was in fact arranged by Dr. Gruen, a close relative. Gruen et al. participated in Dr. Grundfest's experiments. Thereafter, Gruen et al., none of whom had any medical or surgical training, clandestinely and unbeknownst to Grundfest et al., filed a patent application relating to heat surgery which became the Gruen patent.

29. Shortly after the June 25, 1983 experiments, Cedars made efforts to persuade Argonne to enter into a joint, collaborative research project with Cedars to follow up the June 25, 1983 findings with further research. Argonne's Dr. Gruen, in correspondence with Cedars on that topic,

characterized the fact that Cedars had been allowed into the laboratory for the June 25 work as something he had accomplished "by trading on the goodwill of the Laboratory and that of [his] colleagues." Dr. Gruen stated that the further collaboration which Cedars sought would require "a more formal arrangement involving normal Laboratory processes and policies already set up for numerous programs Argonne has with other institutions," the setting up of which would require the discussion of "detailed procedures" with "appropriate Laboratory management." After further efforts by Cedars in hope of bringing such an arrangement about, Argonne informed Cedars that Argonne was unwilling to enter into a collaborative research arrangement with Cedars regarding laser angioplasty. At no time before, during or for many years after the June 25, 1983 experiment session at Argonne did anyone advise plaintiffs or any of them that Argonne, DOE or Gruen, et al. regarded the June 25 session as anything more than a goodwill gesture and a nominal collegial interchange, or that the session, or anything else that transpired between Argonne personnel and Cedars personnel, was regarded by DOE as grounds to assert that the Government owned the fruits of any such cooperation.

30. For several years after the time of the mid-1983 purported events which the DOE Determination describes, DOE said and did nothing to indicate to Plaintiffs or any of them that DOE believed or intended to assert that title to the Invention had vested, could vest, or should vest in the Government.

31. By long inaction and expressions of non-interest in forming a collaborative research project, DOE induced in the plaintiffs a reasonable and justifiable belief that DOE did not believe, and would not assert, that title to

the Invention had vested, could vest, or should vest in the Government, as well as a reasonable and justifiable belief that plaintiffs had full right to practice, develop, disseminate, and improve the invention and would own any patent that might issue in respect of it.

32. In justifiable and detrimental reliance on such beliefs induced by DOE's long inaction and expressions of non-interest in forming a collaborative research project, plaintiffs expended much time, effort and money to practice, develop, disseminate and improve the Invention by, *inter alia*, pursuing patent rights in this and many other countries, obtaining numerous foreign patents covering the Invention in many foreign countries including Australia, Austria, Belgium, France, Germany, Luxembourg, Netherlands, Sweden, Switzerland, Liechtenstein, and United Kingdom, pursuing and ultimately obtaining FDA recommendation of clinical treatment methods which utilized the Invention, building, at a cost of tens of millions of dollars, a laser laboratory at Cedars for the purpose of improving and developing laser angioplasty and disseminating knowledge about it to the medical community, and training and deploying personnel to administer patient care through the use of laser angioplasty.

33. By reason of the foregoing, DOE is barred by laches, estoppel and waiver from asserting that title to the Invention has vested in the Government and from seeking to cause such title so to vest.

(Inapplicability of 42 USC § 5908)

34. Cedars is a "nonprofit organization" within the meaning of 35 USC § 201(i).

35. Upon information and belief, the matter of Government acquisition of title to inventions made by nonprofit organizations is prescribed and governed by Chapter 18 of Title 35 of the united States Code (35 USC §§ 200 ff.), which chapter, by reason of 35 USC § 210(a)(12), takes precedence over any other Act (including the Federal Nonnuclear Energy Research and Development Act of 1974 (42 USC §§ 5901 ff.) which would require a disposition of rights in the subject Invention in a manner inconsistent with said Chapter 18 of Title 35.

36. The Federal Nonnuclear Energy Research and Development Act of 1974 (42 USC §§ 5901 ff.) ("NERDA") would, if applicable, require a disposition of rights in the Invention in a manner inconsistent with Chapter 18 of Title 35, for the reason, *inter alia*, that NERDA would permit the Government to assert title to the Invention even in the absence of a "funding agreement" as defined in 35 USC § 201(b), whereas said Chapter 18 of Title 35 does not permit Government assertion of title absent such a "funding agreement," and no such agreement exists in this case.

37. By reason of the foregoing, 42 USC § 5908 is wholly inapplicable in this case, and the DOE Determination purporting to apply that section is for that reason legally erroneous.

(Injunctive Relief)

38. DOE has acted and, unless enjoined by this Court, will continue to act, in derogation of Plaintiffs' title to the Invention by asserting and representing that the Government has title to the Invention and power to dispose of the Invention.

39. Unless DOE is restrained and enjoined from acting in derogation of Plaintiffs' title to the Invention by asserting and representing that the Government has title to the Invention and power to dispose of the Invention, Plaintiffs will suffer irreparable harm for which they lack an adequate remedy at law, for reasons including the following: Difficulty in disseminating the technology to which the invention relates due to doubts on the part of physicians and surgeons, hospitals, potential manufacturers, financiers, consultants, potential licensees and others as to whether Plaintiffs have the right to practice, disseminate and otherwise deal with that technology.

FIRST CAUSE OF ACTION
(To Set Aside Agency Action Under Administrative Procedure Act, 28 USC § 706(2))

40. Paragraphs 1 through 39 hereof are hereby realleged as if set forth herein at length.

41. The DOE Determination is a "final agency action for which there is no other adequate remedy in a court" within the meaning of 5 USC § 704, and is subject to judicial review under the Administrative Procedure Act.

42. The making of the DOE Determination was arbitrary, capricious and othervise not in accordance with law; was contrary to constitutional right and power, particularly as regards the standards of procedural fairness mandated by the Due Process Clause of the United States Constitution; was in excess of statutory jurisdiction, authority and limitations; and was made without observance of procedure required by law.

SECOND CAUSE OF ACTION
(Declaratory Judgment -- 28 USC § 2201)

43. Paragraphs 1 through 39 hereof are hereby realleged as if set forth herein at length.

44. By reason of the foregoing, an actual controversy exists between the plaintiffs, on the one hand, and the defendant, on the other hand, as to the following issues:

(a) Whether 42 USC § 5908 does or does not govern the rights of the plaintiffs in the circumstances of this case;

(b) Whether the DOE Determination was or was not unlawfully made;

(c) If 42 USC §5908 does not govern the rights of the plaintiffs in the circumstances of this case, whether those rights are governed by Chapter 18 of Title 35 of the United States Code (35 USC § 200 ff.);

(d) If Chapter 18 of Title 35 of the United States Code does govern the rights of the plaintiffs in the circumstances of this case, whether DOE is ineligible to initiate steps toward asserting title to the Invention by reason of failure to enter into a funding agreement with plaintiffs;

(e) Whether DOE is or is not barred by laches, estoppel and/or waiver from asserting that the Government has title to the Invention.

PRAYER FOR RELIEF

WHEREFORE plaintiffs pray for relief as follows:

1. Upon the First Cause of Action, for judgment holding unlawful, and setting aside in all respects, the DOE Determination.

2. Upon the Second Cause of Action, for judgment declaring:

(a) That 42 USC 5908 is inapplicable to the plaintiffs in the circumstances of this case;

(b) that the DOE Determination was not lawfully made and that it is absolutely null, void, and without force or effect;

(c) that the DOE does not have, and cannot lawfully assert, title to the Invention under Title 18 of chapter 35 of the United States Code because the DOE never entered into a funding agreement with plaintiffs or any of them; and

(d) that DOE is barred by laches, estoppel and waiver from asserting that the Government has title to the Invention under NERDA, under Title 18 of chapter 35 of the United States

Code, or under any other provision of law which pertains to Government assertion of title to an invention by reason of Government-aided research.

3. Upon both the First and the Second Causes of Action, for a judgment permanently restraining and enjoining DOE from asserting, or taking steps to assert, title to the Invention, and from taking any other steps in derogation of Cedars' enjoyment of ownership of the Invention, save for participation in Interference No. 102,459.

4. For judgment awarding plaintiffs their costs and disbursements incurred in this action, together with such other and further relief as the Court deems just.

JURY DEMAND

Pursuant to F.R.Civ.P. 38(b), Plaintiffs hereby demand trial by jury of all issues so triable.

Respectfully submitted,

LYON & LYON
A Partnership Including
COE A. BLOOMBERG
A Professional corporation
JERROLD B. REILLY
LOIS M. KWASIGROCH
611 W. Sixth Street
34th Floor
Los Angeles, CA 90017
Tel: (213) 489-1600

Dated: January 9, 1992

By /s/ Coe A. Bloomberg
COE A. BLOOMBERG
Attorneys for Plaintiffs,
CEDARS-SINAI MEDICAL CENTER, et al.

EXHIBIT A

The New York Times, Tuesday, January 29, 1985

SCIENCE TIMES

LASER IS DESIGNED TO CLEAN ARTERIES

[Figure Omitted]

By Sandra Blakeslee
Special to The New York Times

Los Angeles, Jan. 28 -- Millions of Americans have clogged arteries that will inexorably lead to serious heart disease. For a significant number of them, the only available treatment is a risky, costly procedure called coronary bypass surgery in which a vein is removed from the leg and used to construct a detour around a badly blocked artery.

Now, however, important progress has been made on an experimental technique that someday could, without surgery, ream out clogged arteries as deftly as a plumber's snake clears blocked pipes.

The technique, called laser coronary angioplasty, uses a laser attached to flexible glass fibers, encased in a catheter that can be threaded through arteries to reach the material, called plaque, that blocks blood flow. The laser's energy is fired through the fibers to obliterate the plaque, but without the usual laser heat that can damage surrounding tissues.

The technique has not yet been used on living human patients and such tests are not expected for at least 18 months. If those tests are fully successful, it will still be

several years before the technique gains widespread public use, according to physicians and scientists developing the device at the Cedars-Sinai Medical Center in Los Angeles and the Jet Propulsion Laboratory in Pasadena. Nevertheless, the researchers say they have succeeded in building a prototype of a device that will do what no previous design could do. Their experimental device includes a laser that vaporizes plaque at low temperature, and flexible glass fibers that not only carry the laser's energy to the plaque but also light up and produce a video image of the blockage so that the physician can see it before blasting it away.

They say they have, for the first time, made the fibers thin enough to be threaded through smaller arteries where plaque most commonly accumulates. The technique extends the eyes, hands and scalpel of the heart specialist into the human body without surgery, said Dr. James Forrester, director of cardiovascular research at the medical center.

'Could Revolutionize Treatment'

Dr. Forrester said the device has been used successfully to clear arteries freshly excised from heart attack victims, and has been threaded through the arteries of cadavers and living animals.

Claude L'Enfant, director of the National Heart, Lung and Blood Institute of the National Institutes of Health in Bethesda, Md., said in an interview that the technique "still has to be proven safe." But he added, "The Cedars people do good work and we are following what they are doing with great interest."

In 1982, the last year for which figures are available, about 170,000 people underwent coronary bypass surgery at a cost of about $20,000 a person. Some 5 percent to 10 percent of the people who are candidates for bypass surgery

can undergo a less invasive and less expensive procedure that uses a balloon on the tip of a catheter threaded through the arteries. When the balloon is inflated, it presses the plaque to the arterial wall.

But according to Dr. Robertson and other heart experts, the balloon technique works best for those with a single plaque deposit. Most Americans with arteriosclerosis have multiple clogs throughout their arteries. Although some people would still require bypass surgery, the availability of the laser technique means "the necessity of open surgery could be avoided by many patients," Dr. Robertson said, and the nation's health bill could be reduced.

When perfected, the laser-fiber optic device might cost $100,000, its developers said. A patient could have his arteries reamed out in minutes, possibly without an overnight hospital stay.

Lasers are used in many medical specialties where precision cutting or welding is required. But until recently they have not been considered for the treatment of cardiovascular disease for several reasons. Laser energy perforates delicate arteries too easily. When plaque is successfully burned away with most lasers, a rough surface is left that tends to reaccumulate the waxy substance.

Finally, no guidance system is commercially available for carrying a laser's energy to the small coronary arteries. Several research groups throughout the country are working on these problems using argon lasers.

But 18 months ago, two physicians from Cedars-Sinai, Warren Grundfest, a 32-year-old surgeon, and Frank Litvack, 29, a cardiologist, decided on a different tactic.

"We recognized that present laser technology will not succeed," Dr. Grundfest said, because cardiologists need more precision and control to clear an artery than is available with

current medical lasers. They also need something that cuts without high heat.

The doctors found what they needed at the nearby Jet Propulsion Laboratory. Called an excimer (for exciter dimer) laser, it produces short, intense bursts of ultraviolet light so "cool" it can blast away the phosphorus molecules on the head of a match without igniting it.

Such lasers can shatter inorganic compounds by breaking apart the chemical bonds that hold all molecules together. They are used to etch silicon chips, to sample distant molecules in the atmosphere and in so-called "Star Wars" research.

A J.P.L. team consisting of James Laundenslager, Thomas Pacala, Stuart McDermid and David Rider went to work and designed "the perfect laser for heart disease," Dr. Grundfest said. Using a new technology of glass magnetic switches, their xenon chloride excimer laser produces a uniform beam of energy that can be controlled and pulsed in an extremely short period, from 10 billionths of a second to 200 billionths of a second.

One pulse, Dr. Grundfest said, cuts away microns of tissue with great precision, thereby reducing the danger of perforation. In experiments, a typical coronary blockage has been cleared in two minutes.

Also, the new excimer laser does not subject the surrounding tissue to damaging heat, as would, for example, an argon laser, which produces a continuous energy wave at hundreds of degrees centigrade. Under the argon laser, tissue blanches, melts, boils and fries, and craters of blast injury remain.

The next step was to design a "delivery system" that would bring the laser energy to the plaque, but first allowing the surgeon to see what it looks like. "If I can't see what I'm

doing, the system is no good," Dr. Grundfest said. "I don't want to put holes in the arterial wall."

A second collaboration with Tsvi Goldenberg, a hired expert in optical fibers, has led to a 1.5 millimeter-diameter catheter that encases bundles of bendable glass fibers. One group of fibers carries the laser energy. Another shines a light on the tip of the catheter. A third uses a lens on the tip to provide video pictures of the field of view. A clear liquid is flushed through the catheter to push back blood as the viewing proceeds.

The great achievement of the California group, according to Federal health officials, is this delivery system. Dr. Goldenberg said his goal is to design a catheter one millimeter across and one that is guaranteed flexible enough to turn tight corners in the cardiovascular network without puncturing arterial walls.

EXHIBIT B

DETERMINATION UNDER 42 U.S.C. 5908

Interference No. 102,459 has been declared by the U.S. Patent and Trademark Office between DOE patent no. 4,686,979 (S-62,372) and the patent applications of Linsker, S.N. 07/198,424, and Grundfest et al., S.N. 07/205,611. The applicants of the Grundfest et al. patent application are Warren S. Grundfest, James S. Forrester, and Frank Litvack of Cedars-Sinai Medical Center.

The inventors of the DOE patent are Dieter M. Gruen, Charles E. Young, and Michael J. Pellin. These inventors are employed by the Argonne National Laboratory operated under contract for DOE by the University of Chicago.

Dr. Warren S. Grundfest contacted Dr. Gruen about using lasers at Argonne National Laboratory to test their effect on human tissue. Dr. Grundfest specifically requested that the NdYAG laser be used. Then, at the suggestion of Dr. Gruen, the excimer laser was used. During this test the excimer laser was successfully used to sever human tissue on Saturday, June 25, 1983, at Argonne National Laboratory.

The parties discussed the theory and operation of lasers for severing or ablating human tissue both before and after the test at Argonne. A scientific article based on this work was prepared, and the appropriate attribution of authorship was discussed between Gruen and Forrester.

In Dr. Grundfest's June 3, 1983, letter to Dr. Gruen, he described medical research work involving lasers in which

he had been involved in the Cardiology and Vascular Surgery research groups of Cedars-Sinai Medical Center and his ideas regarding further research in this field. This letter led up to the test at Argonne. Dr. James S. Forrester, Director of the Specialized Center of Research in Ischemic Heart Disease at the Cedars-Sinai Medical Center coauthored a letter dated July 29, 1983, to Dr. Gruen describing the importance of this research to the cardiovascular research community, indicated the desirability of testing a number of candidate lasers in addition to the excimer laser, and requested further access to the Argonne facility for these cardiovascular research studies involving lasers. In a letter dated August 12, 1983, Dr. Forrester advised Dr. Gruen of a proposed joint research grant proposal to study excimer laser beam - atherosclerotic tissue interaction as a follow up to the test at Argonne, with the research funds to be divided equally between Cedars-Sinai and Argonne. He authorized Dr. Grundfest and Dr. Frank Litvack to conduct communication on his behalf concerning this proposal. Dr. Litvack subsequently communicated with Dr. Gruen concerning a scientific article about the research that had been performed.

Section 9(a) of the Federal Nonnuclear Research and Development Act of 1974, Pub.L. 93-577, 42 U.S.C. 5908, provides that title to inventions made in the course of or under a contract (defined in Section 9(m) as "any contract, grant, agreement, understanding, or other arrangement ...") shall vest in the United States if the Secretary determines that

(1) the person who made the invention was employed or assigned to perform research, development, or demonstration work and the invention is related to the work he was employed or assigned to perform, or that it was within the scope of his employment duties, whether or not it was

made during working hours, or with a contribution by the Government of the use of Government facilities, equipment, materials, allocated funds, information proprietary to the Government, or services of Government employees during working hours; or

(2) the person who made the invention was not employed or assigned to perform research, development, or demonstration work, but the invention is nevertheless related to the contract or to the work or duties he was employed or assigned to perform, and was made during working hours, or with a contribution from the Government of the sort referred to in clause (1).

Based on the facts set forth above, it is determined that the activities of Grundfest, Forrester, and Litvak in relation to the invention were carried out with a contribution by the Government of the use of Government facilities, equipment, materials and allocated funds and that the invention is related to the arrangement or understanding under which the participants in the research operated and the work they performed and therefore that the invention, if it was made by Grundfest, Forrester, and Litvak, was made in the manner specified in 42 U.S.C. 5908. This determination does not intend any implication that Grundfest, Forrester, and Litvak made the invention.

Grundfest, Forrester, and Litvak may request reconsideration of this determination, stating in detail the reasons therefor [sic], with documentation controverting the facts set forth above or establishing additional facts. Any such request for reconsideration shall be submitted to Assistant General Counsel for Intellectual Property of the

U.S. Department of Energy within thirty (30) days from the date set forth below.

/s/ Richard E. Constant
Richard E. Constant
Assistant General Counsel
for intellectual Property

Date: 12/10/91

APPENDIX G

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Gruen et al.,	)	
Junior Party	)	Interference No. 102,459
	)	
v.	)	Examiner-in-Chief:
	)	
Linsker,	)	John C. Martin
Junior Party	)	
	)	
v.	)	
	)	
Grundfest et al.,	)	
Senior Party	)	

AFFIDAVIT

Commissioner of Patents and Trademark
Washington, D.C. 20231

Sir:

I, Fred A. Cafasso, affix my signature and declare:

That, I have received a PhD from New York University in physical chemistry in 1959.

That, I am a resident of the village of Oak Park, in the county of Cook and the state of Illinois.

That, I am an employee of Argonne National Laboratory, in Argonne, Illinois.

That, I am presently employed as Deputy Division Director of the Chemistry Division of Argonne National Laboratory.

That, during the time period from about May 30, 1983 to about July 1, 1983, I held joint appointments as an Associate Director of The Chemistry Division, an Associate Director of Chemical Technology Division and an Associate Director of Materials Science Division of Argonne National Laboratory.

That, during this time period, Dr. Dieter M. Gruen came to me and told me that he had been contacted by a Dr. W. Grundfest about the use of Nd-YAG pumped dye lasers to unplug human arteries. Dr. Gruen told me that Dr. Grundfest wished to come to Argonne Laboratory to use the laser equipment. Dr. Gruen stated that he together with Dr. Charles Young and Dr. Michael Pellin were willing to come in on a Saturday and work with Dr. Grundfest, and requested my permission for them to do so.

That, I concluded that it was worthwhile to do the exploratory experiments since it was outside of the scope of work being conducted in the chemistry division at the time and since they wished to come in at a time other than regular business hours to do the work and so would not disrupt the normal laboratory activities.

That, I gave permission for Drs. Gruen, Young and Pellin to meet with Dr. Grundfest on a Saturday at the laboratory and to use the laboratory laser equipment, provided

the procedures set forth in the ANL Health and Safety Manual and the Chemistry Division Safety Procedures in effect at that time were followed.

That, I was later given positive feedback that the experiments done on that Saturday were successful.

That, Argonne National Laboratory has no formal written policy regarding short-term collaborative efforts between Argonne scientists and scientists from organizations outside of Argonne, however, Argonne does have an unwritten policy of encouraging nominal collegial interchanges.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury, that the foregoing is true and correct.

/s/ Fred A. Cafasso
Fred A. Cafasso
Deputy Division Director
Chemistry Division
Argonne National Laboratory

Executed on: Dec. 17, 1991

APPENDIX H

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

LYON & LYON
A Partnership Including
COE A. BLOOMBERG
A Professional Corporation
JERROLD B. REILLY
LOIS M. KWASIGROCH
611 West Sixth Street
34th Floor
Los Angeles, California 90017
(213) 489-1600

FILED
CLERK,
U.S. DISTRICT COURT

MAR 19 1992

CENTRAL DISTRICT
OF CALIFORNIA

Attorneys for Plaintiffs,
CEDARS-SINAI MEDICAL CENTER, et al.

CEDARS-SINAI MEDICAL CENTER, a not-for-profit California corporation, WARREN S. GRUNDFEST, M.D., JAMES S. FORRESTER, M.D., and FRANK LITVACK, M.D.,

Plaintiffs,

v.

JAMES D. WATKINS,
Secretary of the United States Department of Energy,

Defendant.

Case No. 92-0154 JGD(EX)

AFFIDAVIT OF PAUL M. YAEGER

I, PAUL M. YAEGER, having been first duly sworn, hereby depose and state:

1. That I am a Vice President of Cedars-Sinai Medical Center (hereafter "Cedars") located at 8700 Beverly Boulevard in Los Angeles, California, one of the named plaintiffs in this action;

2. That I was principally responsible for the creation of the Cedars patent policy, which is generally described in an article, which I coauthored, appearing in the *New England Journal of Medicine*, a reprint of which is attached as Exhibit A;

3. That Cedars is a not-for-profit California corporation, and attached as Exhibits B and C are copies of a Federal Internal Revenue Charitable tax exempt status notification made under Internal Revenue Code Section 501(c)(3) and the not-for-profit California Articles of Incorporation for Cedars and its predecessor institutions dating back to 1902;

4. That the principal purpose of Cedars, as stated in its corporate bylaws since 1902, has been service to the community;

5. That Cedars created its patent policy in furtherance of its purpose of community service in order to license its patented technology to reputable pharmaceutical and medical product manufacturers and make the fruits of its medical research available to the public;

6. That at present, the Cedars patent portfolio includes over 50 patents and approximately 170 pending patent applications in the United States and numerous foreign countries directed to such areas of medicine as diagnostic immunoassays, kidney disease treatment, surgical bandages, Alzheimer's disease treatment, viral inactivation of blood components and AIDS treatment;

7. That licensees of Cedars patented technology include Johnson & Johnson, Miles Laboratories, Baxter-Travenol, Armour Pharmaceutical, Alpha Therapeutics and Immuno Aktiengesselschaft;

8. That Cedars has licensed its patented technology on a royalty-free basis to sister not-for-profit institutions such as the American Red Cross and affiliated foreign Red Cross organizations in Canada and Europe;

9. That income from royalty bearing patent licenses is utilized by Cedars for further research funding, as well as for the funding of indigent patient care and the Cedars trauma care center.

FURTHER AFFIANT SAYETH NOT.

2/24/92
Date

/s/ Paul M. Yaeger
Paul M. Yaeger

STATE OF CALIFORNIA)
) ss.
COUNTY OF LOS ANGELES)

Sworn to before me this 24 day of February, 1992.

/s/ Judson E. Capell
Notary Public

(Notarial Seal)

APPENDIX I

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

LYON & LYON
A Partnership Including
COE A. BLOOMBERG
A Professional Corporation
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FILED
CLERK,
U.S. DISTRICT COURT

APR 13 1992

CENTRAL DISTRICT
OF CALIFORNIA

Attorneys for Plaintiffs,
CEDARS-SINAI MEDICAL CENTER, et al.

CEDARS-SINAI MEDICAL CENTER, a not-for-profit California corporation, WARREN S. GRUNDFEST, M.D., JAMES S. FORRESTER, M.D., and FRANK LITVACK, M.D.,

Plaintiffs,

v.

JAMES D. WATKINS,
Secretary of the United States Department of Energy,

Defendant.

Case No. 92-0154 JGD(EX)

SECOND AFFIDAVIT OF PAUL M. YAEGER

I, Paul M. Yaeger, hereby depose and state:

That I am the same Paul Yaeger who earlier submitted an affidavit in this matter dated February 17, 1992;

That in my capacity as a Cedars Vice President, I have successfully negotiated third party licenses regarding pending patent applications which have resulted in royalty payments to the Medical Center measured in the tens of millions of dollars;

That I am currently involved in third party negotiations relating to Cedars U.S. Patent Application Serial No. 559,430 which is the subject of the DOE December 10, 1991 Determination under § 5908; and

That the § 5908 Determination has had a pronounced negative impact on such licensing negotiations which I believe will either greatly reduce the royalty income to the Medical Center or prevent the conclusion of any license agreement.

FURTHER AFFIANT SAYETH NOT.

/s/ Paul M. Yaeger
Paul M. Yaeger

Sworn to before me
this 1st day of
April 1992

/s/ Judson E. Capell
Notary Public

(Notarial Seal)

APPENDIX J

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

LYON & LYON
A Partnership Including
COE A. BLOOMBERG
A Professional Corporation
JERROLD B. REILLY
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611 West Sixth Street
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Los Angeles, California 90017
(213) 489-1600

Attorneys for Plaintiffs,
CEDARS-SINAI MEDICAL CENTER, et al.

CEDARS-SINAI MEDICAL CENTER,
a not-for-profit California corporation; WARREN S. GRUNDFEST, M.D.; JAMES S. FORRESTER, M.D.; and FRANK LITVACK, M.D.,
Plaintiffs,

v.

JAMES D. WATKINS,
Secretary, United States Department of Energy,
Defendant.

STATE OF CALIFORNIA)
) ss.
COUNTY OF LOS ANGELES)

Case No. 92-0154 JGD(EX)
Hearing Date: May 11, 1992
Hearing Time: 1:30 p.m.
Hearing Place: Courtroom of Judge Davies

AFFIDAVIT OF COE A. BLOOMBERG

I, Coe A. Bloomberg, having been duly sworn, hereby declare and state:

That I am lead counsel for Plaintiffs in this matter and am the same person who executed an affidavit previously filed in this action;

That I am the partner at Lyon & Lyon responsible for the filing and prosecution of Cedars-Sinai patent applications, both in the United States and in foreign countries;

That Cedars-Sinai United States Patent Application Serial No. 559,430, filed on December 8, 1983, is the subject of the December 10, 1991 DOE Determination;

That attached hereto as EXHIBIT A is Cedars-Sinai Australian Patent No. 580,575, which is the Australian equivalent of U.S. Patent Application Serial No. 559,430, which Australian patent is based on the U.S. Application Serial No. 559,430, as noted on the first page of the patent;

That attached hereto as EXHIBIT B is Cedars-Sinai European Patent No. 165,301, which is the European equivalent of U.S. Application Serial No. 559,430, and designates Austria (AT), Belgium (BE), France (FR), Germany (GE), Luxembourg (LU), Netherlands (NL), Sweden (SE), Switzerland (CH), Liechtenstein (LI), and the United Kingdom (GB); and that this European patent is based on the U.S. Application Serial No. 559,430, which fact is noted on the first page of the patent;

That in addition to having already-issued patents in the eleven foreign countries mentioned above, Cedars-Sinai has a patent application pending in Japan, attached hereto as EXHIBIT C, which is the Japanese equivalent of, and is based on, United States Patent Application Serial No. 559,430;

That Cedars-Sinai's Australian and European patents had already issued, and its Japanese application had already been filed, before the December 10, 1991 date of the DOE Determination; and

That attached hereto as EXHIBIT D is a true and correct copy of the transcript of the deposition of William R. Moser, which I conducted on April 30, 1992.

FURTHER AFFIANT SAYETH NOT.

/s/ Coe A. Bloomberg
COE A. BLOOMBERG

Subscribed and sworn to before me this 4th day of May, 1992.

/s/ Nada Pearl Robie
NOTARY PUBLIC

(Notarial Seal)

APPENDIX K

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

LOURDES G. BAIRD
United States Attorney
LEON W. WEIDMAN
Assistant United States Attorney
Chief, Civil Division
GEORGE H. WU
Assistant United States Attorney
Assistant Chief, Civil Division
STAN BLUMENFELD
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Attorneys for Defendant

CEDARS-SINAI MEDICAL CENTER, a not-for-profit California corporation, WARREN S. GRUNDFEST, M.D., JAMES S. FORRESTER, M.D., and FRANK LITVACK, M.D.,

Plaintiffs,

v.

JAMES D. WATKINS, Secretary
United States Department of Energy,

Defendant.

Case No. CV 92-0154 JGD(Ex)
Date: May 11, 1992
Time: 1:30 p.m.

(1) NOTICE OF MOTION AND MOTION TO DISMISS PLAINTIFF' COMPLAINT;

(2) MOTION FOR STAY OF PROCEEDINGS;

(3) OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT, AND JUDGMENT ON THE PLEADINGS; and

(4) MEMORANDUM OF POINTS AND AUTHORITIES.

[p. 9]

* * * *

As utilized by the DOE, a Section 5908 determination does not have any immediate consequences nor does it cause any immediate change in the rights of interested parties. The determination is not an administrative order requiring a party to do anything or to refrain from doing anything. The only way in which the DOE (or any person) can obtain control over and exclusive rights in an invention is by obtaining the patent rights for the invention.

* * * *

[p. 20]

* * * *

The plaintiffs' alleged interest is their claimed rights to the laser invention. However, the only legally cognizable rights to any invention arise from the patent which is issued by the United States Patent and Trademark Office. *See Sears, Roebuck & Co., supra,* 376 U.S. at 231. At this time, plaintiffs do not possess any patent in the invention. Indeed, the DOE through

Gruen, et al. now holds the patent in the invention, but that matter is currently before the Board in the interference action.

Therefore, the Section 5908 determination did not and could not invade any legally protected right of the plaintiffs as to the invention. The effect of that determination is merely to notify the plaintiffs of the agency's position that, if the Patent Office holds that the invention was first created by the plaintiffs such that they are entitled to the patent, then DOE's position is that that patent still belongs to the United States since the invention was created with the use of government facilities and the assistance of its personnel. However, the DOE's position is not self-executing nor does it have any immediate legal effect.

* * * *

[p. 35]

* * * *

Dated: April 13, 1992.

LOURDES G. BAIRD
United States Attorney
LEON W. WEIDMAN
Assistant United States Attorney
Chief, Civil Division

/s/ George H. Wu
GEORGE H. WU
Assistant United States Attorney
Attorney for Defendant

APPENDIX L

§ 5908. Patents and inventions

(a) Vesting of title to invention and issuance of patents to United States; prerequisites

Whenever any invention is made or conceived in the course of or under any contract of the Secretary, other than nuclear energy research, development, and demonstration pursuant to the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.) and the Secretary determines that ——

(1) the person who made the invention was employed or assigned to perform research, development, or demonstration work and the invention is related to the work he was employed or assigned to perform, or that it was within the scope of his employment duties, whether or not it was made during working hours, or with a contribution by the Government of the use of Government facilities, equipment, materials, allocated funds, information proprietary to the Government, or services or Government employees during working hours; or

(2) the person who made the invention was not employed or assigned to perform research, development, or demonstration work, but the invention is nevertheless related to the contract or to the work or duties he was employed or assigned to perform, and was made during working hours, or with a contribution from the Government of the sort referred to in clause (1).[1]

title to such invention shall vest in the United States, and if patents on such invention are issued they shall be issued to the United States, unless in particular circumstances the Secretary waives all or any part of the rights of the United States to such invention in conformity with the provisions of this section.

(b) Contract as requiring report to Secretary of invention, etc., made in course of contract

Each contract entered into by the Secretary with any person shall contain effective provisions under which such person shall furnish promptly to the Secretary a written report containing full and complete technical information concerning any invention, discovery, improvement, or innovation which may be made in the course of or under such contract.

(c) Waiver by Secretary of rights of United States; regulations prescribing procedures; record of waiver determinations; objectives

Under such regulations in conformity with the provisions of this section as the Secretary shall prescribe, the Secretary may waive all or any part of the rights of the United States under this section with respect to any invention or class of inventions made or which may be made by any person or class of persons in the course of or under any contract of the Secretary if he determines that the interests of the United States and the general public will best be served by such waiver. The Secretary shall maintain a publicly available, periodically updated record of waiver

determinations. In making such determinations, the Secretary shall have the following objectives.

1) Making the benefits of the energy research, development, and demonstration program widely available to the public in the shortest practicable time.

2) Promoting the commercial utilization of such inventions.

3) Encouraging participation by private persons in the Secretary's energy research, development, and demonstration program.

4) Fostering competition and preventing undue market concentration or the creation or maintenance of other situations inconsistent with the antitrust laws.

(d) Considerations applicable at time of contracting for waiver determination by Secretary

In determining whether a waiver to the contractor at the time of contracting will best serve the interest of the United States and the general public, the Secretary shall specifically include as considerations ———

(1) the extent to which the participation of the contractor will expedite the attainment of the purposes of the program;

(2) the extent to which a waiver of all or any part of such rights in any or all fields of technology is

needed to secure the participation of the particular contractor;

(3) the extent to which the contractor's commercial position may expedite utilization of the research, development, and demonstration program results;

(4) the extent to which the Government has contributed to the field of technology to be funded under the contract;

(5) the purpose and nature of the contract, including the intended use of the results developed thereunder;

(6) the extent to which the contractor has made or will make substantial investment of financial resources or technology developed at the contractor's private expense which will directly benefit the work to be performed under contract;

(7) the extent to which the field of technology to be funded under the contract has been developed at the contractor's private expense;

(8) the extent to which the Government intends to further develop to the point of commercial utilization the results of the contract effort;

(9) the extent to which the contract objectives are concerned with the public health, public safety, or public welfare;

(10) the likely effect of the waiver on competition and market concentration; and

(11) in the case of nonprofit educational institution, the extent to which such institution has a technology transfer capability and program, approved by the Secretary as being consistent with the applicable policies of this section.

(e) Considerations applicable to identified invention for waiver determination by Secretary

In determining whether a waiver to the contractor or inventor of rights to an identified invention will best serve the interests of the United States and the general public, the Secretary shall specifically include as considerations paragraphs (4) through (11) of subsection (d) of this section as applied to the invention and ———

(1) the extent to which such waiver is a reasonable and necessary incentive to call forth private risk capital for the development and commercialization of the invention; and

(2) the extent to which the plans, intentions, and ability of the contractor or inventor will obtain expeditious commercialization of such invention.

(f) Rights subject to reservation where title to invention vested in United States

Whenever title to an invention is vested in the United States, there may be reserved to the contractor or inventor ——

(1) a revocable or irrevocable nonexclusive, paid-up license for the practice of the invention throughout the world; and

(2) the rights to such invention in any foreign country where the United States has elected not to secure patent rights and the contractor elects to do so, subject to the rights set forth in paragraphs (2), (3), (6), and (7) of subsection (h) of this section: *Provided,* That when specifically requested by the Secretary and three years after issuance of such a patent, the contractor shall submit the report specified in subsection (h)(1) of this section.

(g) to (i) Repealed. Pub.L. 96-517, § 7(c), Dec. 12, 1980, 94 Stat. 3027

(j) Small business status of applicant for waiver or licenses

The Secretary shall, in granting waivers or licenses, consider the small business status of the applicant.

(k) Protection of invention, etc., rights by Secretary

The Secretary is authorized to take all suitable and necessary steps to protect any invention or discovery to which the United States holds title, and to require that contractors or persons who acquire rights to inventions under this section protect such inventions.

(l) Secretary as defense agency of United States for purpose of maintaining secrecy of inventions

The Secretary shall be considered a defense agency of the United States for the purpose of chapter 17 of Title 35.

(m) Definitions

As used in this section ——

(1) the term "person" means any individual, partnership, corporation, association, institution, or other entity;

(2) the term "contract" means any contract, grant, agreement, understanding, or other arrangement, which includes research, development, or demonstration work, and includes any assignment, substitution of parties, or subcontract executed or entered into thereunder;

(3) the term "made", when used in relation to any invention, means the conception or first actual reduction to practice of such invention;

(4) the term "invention" means inventions or discoveries, whether patented or unpatented; and

(5) the term "contractor" means any person having a contract with or on behalf of the Secretary.

(n) Report concerning applicability of existing patent policies to energy programs; time for submission to President and appropriate congressional committees

Within twelve months after December 31, 1974, the Secretary with the participation of the Attorney General, the Secretary of Commerce, and other officials as the President may designate, shall submit to the President and the appropriate congressional committees a report concerning the applicability of existing patent policies affecting the programs under this chapter, along with his recommendations for amendments or additions to the statutory patent policy, including his recommendations on mandatory licensing, which he deems advisable for carrying out the purposes of this chapter.

(Pub.L. 93-577, § 9, Dec. 31, 1974, 88 Stat. 1887; Pub.L. 95-91, Title III, § 301(a), Title VII, § 703, 707, Aug. 4, 1977, 91 Stat. 577, 606, 607; Pub.L. 96-517, § 7(c), Dec. 12, 1980, 94 Stat. 3027.)

[1] So in original. Probably should be a comma.

Supreme Court, U.S.
FILED
JUN 6 1994
OFFICE OF THE CLERK

No. 93-1450

In the Supreme Court of the United States

OCTOBER TERM, 1993

CEDARS-SINAI MEDICAL CENTER, ET AL., PETITIONERS

v.

HAZEL O'LEARY, SECRETARY OF ENERGY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether the court of appeals correctly applied the two-part test set forth in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967), in concluding that petitioners' challenge to a Department of Energy determination of government patent rights, made pursuant to 42 U.S.C. 5908, was not ripe for adjudication.

TABLE OF CONTENTS

	Page
Opinions below	1
Jurisdiction	1
Statement	2
Argument	6
Conclusion	12

TABLE OF AUTHORITIES

Cases:

Abbott Laboratories v. *Gardner*, 387 U.S. 136 (1967)	4, 7, 8
Air New Zealand Ltd. v. *CAB*, 726 F.2d 832 (D.C. Cir. 1984)	6, 10
Alascom, Inc. v. *FCC*, 727 F.2d 1212 (D.C. Cir. 1984)	10
American Fed'n of Gov't Employees v. *FLRA*, 750 F.2d 143 (D.C. Cir. 1984)	9
American Trucking Ass'ns v. *ICC*, 747 F.2d 787 (D.C. Cir. 1984)	10
ANR Pipeline Co. v. *FERC*, 876 F.2d 124 (D.C. Cir. 1989)	6, 9
Baltimore Gas & Elec. Co. v. *ICC*, 672 F.2d 146 (D.C. Cir. 1982)	10
Consolidation Coal Co. v. *Federal Mine Safety & Health Review Comm'n*, 824 F.2d 1071 (D.C. Cir. 1987)	9, 11
Eagle-Picher Indus., Inc. v. *United States EPA*, 759 F.2d 905 (1985)	10
EPA v. *National Crushed Stone Ass'n*, 449 U.S. 64 (1980)	8
Gardner v. *Toilet Goods Ass'n*, 387 U.S. 167 (1967)	7, 8
Goodman v. *Lukens Steel Co.*, 482 U.S. 656 (1987)	11
Harrison v. *PPG Indus., Inc.*, 446 U.S. 578 (1980)	8
Her Majesty the Queen v. *United States EPA*, 912 F.2d 1525 (D.C. Cir. 1990)	10

Cases—Continued: Page

National Recycling Coalition, Inc. v. *Browner*, 984 F.2d 1243 (D.C. Cir. 1993) 10
National Recycling Coalition, Inc. v. *Reilly*, 884 F.2d 1431 (D.C. Cir. 1989) 10-11
Pacific Gas & Elec. Co. v. *State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190 (1983) 7
Poe v. *Ullman*, 367 U.S. 497 (1961) 8
Public Citizen, Inc. v. *U.S. Nuclear Regulatory Comm'n*, 940 F.2d 679 (D.C. Cir. 1991) 9
Regional Rail Reorganization Act Cases, 419 U.S. 102 (1974) 7
Reno v. *Catholic Social Servs., Inc.*, 113 S. Ct. 2485 (1993) 7
South Carolina Elec. & Gas Co. v. *ICC*, 734 F.2d 1541 (D.C. Cir. 1984) 10
Tenneco Gas v. *FERC*, 969 F.2d 1187 (D.C. Cir. 1992) 9
Tennessee Gas Pipeline Co. v. *FERC*, 736 F.2d 747 (D.C. Cir. 1984) 10
Thunder Basin Coal Co. v. *Reich*, 114 S. Ct. 771 (1994) 12
Thomas v. *Union Carbide Agric. Prods. Co.*, 473 U.S. 568 (1985) 8
Toilet Goods Ass'n v. *Gardner*, 387 U.S. 158 (1967) 6, 7, 8
United States v. *Doe*, 465 U.S. 605 (1984) 11
United States v. *Fausto*, 484 U.S. 439 (1988) 11
Western Elec. Co. v. *Piezo Technology, Inc.*, 860 F.2d 428 (Fed. Cir. 1988) 3

Statutes:

Administrative Procedure Act, 5 U.S.C. 701-706 .. 4
Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. 9601 *et seq.* .. 10
Federal Nonnuclear Energy Research and Development Act of 1974, Pub. L. No. 93-577, § 9, 88 Stat. 1878 (42 U.S.C. 5908) 3, 11
42 U.S.C. 5908(a) 3
42 U.S.C. 5908(m)(2) 3

Statutes—Continued: Page

28 U.S.C. 1295(a)(1) 11
28 U.S.C. 2201 4
35 U.S.C. 135 3

Miscellaneous:

Erwin Chemerinsky, *Federal Jurisdiction* (1989).. 8

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v.

HAZEL O'LEARY, SECRETARY OF ENERGY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A1-A27) is reported at 11 F.3d 1573. The opinion of the district court (Pet. App. B1-B8) is unpublished.

JURISDICTION

The judgment of the court of appeals was entered on December 13, 1993. The petition for a writ of certiorari was filed on March 11, 1994. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. In June, 1983, petitioner Warren S. Grundfest, M.D., conducted an experiment in the field of laser angioplasty at the Argonne National Laboratory, a government-owned facility operated by the University of Chicago under contract with the Department of Energy (DOE), with the participation of Dr. Dieter M. Gruen, an employee of the Argonne facility who had arranged Dr. Grundfest's visit to the facility.[1] Following the experiment, both Dr. Grundfest and Dr. Gruen filed applications to patent the laser angioplasty technique. Ralph Linsker, a third party who took no part in the Argonne experiment, also sought to patent a similar invention. Pet. App. A3-A4, B2-B3.

On August 18, 1987, United States Patent No. 4,686,979, entitled "Excimer Laser Phototherapy for the Dissolution of Abnormal Growth," was issued to the government, as assignee of Dr. Gruen's application. Following the issuance of the patent, petitioner Cedars-Sinai Medical Center (Cedars)—Dr. Grundfest's employer and the assignee of his patent application—initiated an Interference action in the Patent and Trademark Office (PTO) to determine who first invented the laser angioplasty technique.[2] On Sep-

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[1] Laser angioplasty is a technique through which laser energy is used to treat clogged arteries. Pet. App. F22. In the course of the experiment at the Argonne facility, Dr. Gruen made the critical suggestion that the excimer laser be selected from among the many lasers present at the Argonne facility. *Id.* at F27.

[2] An Interference is a quasi-judicial proceeding before the PTO's Board of Patent Appeals and Interferences to deter-

tember 10, 1991, the PTO's Board of Patent Appeals and Interferences (Board) declared (accepted for determinaton) Interference No. 102,459 (the Interference) between Dr. Grundfest, Dr. Gruen, and Linsker.[3] Pet. App. A3-A4, B2-B3.

2. Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974, Pub. L. No. 93-577, 88 Stat. 1878, provides *inter alia* that when any invention is made in the course of an arrangement or understanding with the Secretary of Energy (Secretary), and the Secretary determines that the invention was made with a contribution by the government or the use of government facilities, title to the invention shall vest in, and any patents on the invention shall issue to, the United States. 42 U.S.C. 5908 (a) and (m)(2). On December 10, 1991, because of the Interference initiated by petitioners, and pursuant to Section 5908, the DOE rendered and served upon petitioners a Determination that, if in fact it was Dr. Grundfest who invented the laser angioplasty technique, the invention was made in the manner specified in Section 5908 (the Determination). Pet. App. F27-F30. The Determination stated that petitioners had 30 days to request reconsideration of the matter. *Id.* at F29-F30. Petitioners failed to do so. *Id.* at A5.

3. Petitioners subsequently filed suit in the United States District Court for the Central District of Cali-

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mine questions of priority of invention and patentability. See 35 U.S.C. 135; *Western Elec. Co.* v. *Piezo Technology, Inc.*, 860 F.2d 428, 431 (Fed. Cir. 1988).

[3] The Interference action is still pending. A decision by the Board in favor of either Dr. Gruen or Linsker will constitute a rejection of petitioners' patent application. 35 U.S.C. 135.

fornia. Pet. App. F1-F21. Petitioners sought both to have the Determination set aside on various grounds under the Administrative Procedure Act, 5 U.S.C. 701-706, and to have a declaratory judgment rendered on several issues under 28 U.S.C. 2201. Pet. App. F17-F19. The district court, after applying the two-pronged test for ripeness set forth in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967), dismissed petitioners' complaint, without prejudice, as unripe. Pet. App. B1-B8.

With respect to the "fitness for judicial resolution" prong of the *Abbott Laboratories* test, the district court concluded that petitioners' suit was premature due to the pending Interference. The court reasoned that if the Board ultimately awards the patent to either Dr. Gruen or Linsker, the Determination would be without consequence.[4] Under the "hardship to the parties" prong of the *Abbott Laboratories* test, the district court concluded that petitioners would suffer no ill effects if a judicial decision were deferred until resolution of the Interference. The district court specifically considered and rejected petitioners' argument that the Determination clouded title to their foreign patents and impaired their ability to license those patents. Pet. App. B6-B7.

4. The court of appeals affirmed. Pet. App. A1-A27. Applying the first prong of the *Abbott Laboratories* ripeness test, the court of appeals agreed with the district court that, with respect to petitioners'

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[4] The court also expressed the view that the Board might resolve the issues raised in the Determination. Pet. App. B6. However, both the Board and the Commissioner of Patents and Trademarks subsequently adopted the position that the Board lacks the authority during an Interference to decide patent ownership questions. *Id.* at A16 n.10, C3, D2-D3, E3.

domestic patent rights, "the effects of the Determination have yet to be felt in any concrete sense" and that "due to the pending Interference, judicial resolution of the issues presented would not in any way alleviate the current cloud" over those rights. Pet. App. A17. The court of appeals concluded, however, that petitioners' case was fit for judicial resolution because the Determination clouded petitioners' foreign patent rights and could adversely affect their ability to license those patents. In this regard, the court noted the Interference was immaterial to petitioners' foreign patent rights.[5] The court of appeals therefore held that the first prong of the *Abbott Laboratories* test was satisfied. Pet. App. A18-A20.

Turning next to the "hardship to the parties" prong of the *Abbott Laboratories* test, the court of appeals determined that petitioners "ha[ve] not demonstrated any immediate harm with respect to its foreign patent rights." Pet. App. A26 n.14. The court of appeals noted that petitioners' complaint and supporting affidavits contained only conclusory statements about its efforts to license its foreign patent rights and that "[c]onclusory statements, standing alone, are insufficient to carry [petitioners'] burden to prove hardship under the second prong of the *Abbott Laboratories* test." *Id.* at A25. Because petitioners failed to satisfy the second prong of the *Abbott Laboratories* test, the court of appeals held that the district court had properly dismissed the case without prejudice as unripe. Pet. App. A27.

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[5] The court of appeals noted that "the issue before the Board is priority of invention, an issue which is irrelevant under the pertinent first-to-file foreign patent laws and which cannot by itself affect the issue of who first *filed* the application for patent." Pet. App. A18.

ARGUMENT

1. Petitioners contend (Pet. 9-15) that the court of appeals misapplied the *Abbott Laboratories* test. In their view, satisfaction of the first prong of that test compels the conclusion that a case is ripe for adjudication and obviates the need to consider the second prong. Petitioners' argument is incorrect.[6]

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[6] Petitioners also suggest (Pet. 10-11) that the courts below should not have employed the *Abbott Laboratories* test at all, on the theory that the test applies only in the context of pre-enforcement challenges to agency regulations. That claim, however, was not considered by either of the courts below. Petitioners have never before questioned the applicability of the *Abbott Laboratories* test (quite the contrary is true, see Pet. C.A. Br. 15-24), and neither of the courts below suggested that the test might be inapplicable here. In any event, although the *Abbott Laboratories* test did arise in the context of preenforcement review of agency regulations, the test has been applied outside of that context. For example, in *Air New Zealand Ltd.* v. *CAB*, 726 F.2d 832 (D.C. Cir. 1984), the court considered an airline's challenge to a proviso contained in an agency order granting the airline authority to provide limited service between Los Angeles, London, and New Zealand. Applying the *Abbott Laboratories* test, then-Judge Scalia, stating that the "doctrine has strong application here," *id.* at 835, determined for the court that the airline's challenge was not ripe. See also *ANR Pipeline Co.* v. *FERC*, 876 F.2d 124, 130-131 (D.C. Cir. 1989) (dismissing as unripe under *Abbott Laboratories* a challenge to a proviso in a certificate authorizing the transportation of imported natural gas).

Petitioners also suggest (Pet. 11-12) that *Abbott Laboratories* is inapplicable here because (1) the Determination was a final agency action and (2) their challenge raises purely legal issues. Those facts, however, do not make the *Abbott Laboratories* test inapplicable. In *Toilet Goods Ass'n* v. *Gardner*, 387 U.S. 158 (1967), this Court held that a challenge to an agency regulation was not ripe, notwithstanding

a. Assuming *arguendo* that the first prong of the *Abbott Laboratories* test was satisfied in this case, there was no legal error in dismissing the suit as unripe on the basis of the second prong alone. The basic rationale of the ripeness doctrine "is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Abbott Laboratories*, 387 U.S. at 148.[7] In *Abbott Laboratories*, which has been described as the "leading discussion of the doctrine," *Pacific Gas & Elec. Co.* v. *State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 201 (1983), the Court laid out a two-part test for assessing the ripeness of a legal challenge.[8] Under that test, a court must "evaluate *both* the fitness of the issues for judicial decision *and* the hardship to the parties of withholding court consideration." 387 U.S. at 149 (emphasis added). As this language suggests, a would-be plaintiff must

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the Court's express recognition of the fact that the regulation was a "final agency action" and the suit presented "a purely legal question." *Id.* at 162, 163.

[7] Although it also has a prudential aspect, the doctrine in some of its applications is compelled by the Constitution's "case or controversy" requirement. See *Reno* v. *Catholic Social Servs., Inc.*, 113 S. Ct. 2485, 2495 n.18 (1993); *Regional Rail Reorganization Act Cases*, 419 U.S. 102, 138 (1974).

[8] The *Abbott Laboratories* test was applied in two other cases decided on the same day. See *Toilet Goods Ass'n* v. *Gardner*, 387 U.S. 158 (1967); *Gardner* v. *Toilet Goods Ass'n*, 387 U.S. 167 (1967).

satisfy both prongs of the test for a suit to be ripe. See also *id.* at 153 ("Where the legal issue presented is fit for judicial resolution, *and* where a regulation requires an immediate and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance, access to the courts * * * must be permitted.") (emphasis added); *Toilet Goods Ass'n* v. *Gardner*, 387 U.S. 158, 164 (1967) ("[T]he test of ripeness, as we have noted, depends *not only* on how adequately a court can deal with the legal issue presented, *but also* on the degree and nature of the regulation's present effect on those seeking relief.") (emphasis added); *Poe* v. *Ullman*, 367 U.S. 497, 508-509 (1961) ("Justiciability * * * is the resultant of many subtle pressures, including the appropriateness of the issues for decision by this Court and the actual hardship to the litigants of denying them the relief sought."); Erwin Chemerinsky, *Federal Jurisdiction* § 2.4, at 108 (1989) ("[T]he Court's decisions seem to indicate that both [ripeness] requirements must be met."). Moreover, in every case in which this Court has applied the *Abbott Laboratories* test and concluded that a dispute was ripe for review—including *Abbott Laboratories* itself—this Court has addressed both the fitness and hardship prongs of the test.[9] If it is true, as petitioners contend, that a dispute is ripe if it satisfies the fitness

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[9] See *Thomas* v. *Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 581 (1985); *Pacific Gas*, 461 U.S. at 201-203; *EPA* v. *National Crushed Stone Ass'n*, 449 U.S. 64, 72 n.12 (1980); *Gardner* v. *Toilet Goods Ass'n*, 387 U.S. 167, 170-174 (1967); *Abbott Laboratories*, 387 U.S. at 148-156; see also *Harrison* v. *PPG Indus., Inc.*, 446 U.S. 578, 603 (1980) (Stevens, J., dissenting).

prong alone, the Court's hardship analysis in each of these cases was superfluous.

b. Petitioners argue (Pet. 12-13, 15) that, by dismissing their suit solely on the basis of the second prong of the *Abbott Laboratories* test, the court of appeals utilized an approach contrary to that employed in the D.C. Circuit. There is, however, no such conflict.

The D.C. Circuit generally follows the rule that a plaintiff must satisfy both the fitness and hardship prongs of the *Abbott Laboratories* test and has on numerous occasions dismissed cases on the basis of the hardship prong alone. See *Tenneco Gas* v. *FERC*, 969 F.2d 1187, 1211 (D.C. Cir. 1992) ("Although *Athlone* [*Indus.* v. *Consumer Prods. Safety Comm'n*, 707 F.2d 1485 (D.C. Cir. 1983)] supports the pipeline petitioners as to the fitness of their claim, they still must show that delay in settling the civil penalties issue will cause them to suffer a hardship."); *Public Citizen, Inc.* v. *U.S. Nuclear Regulatory Comm'n*, 940 F.2d 679, 684 (D.C. Cir. 1991) ("[E]ven assuming that the claim is close enough to fitness for review that a showing of hardship would enable us to eke out a ripeness finding, petitioners have not shown any such hardship."); *ANC Pipeline Co.* v. *FERC*, 876 F.2d 124, 131 (D.C. Cir. 1989) ("We may assume without deciding that the issue is fit for judicial review. * * * We can, however, find no hardship to Great Lakes in postponing review."); *Consolidation Coal Co.* v. *Federal Mine Safety & Health Review Comm'n*, 824 F.2d 1071, 1082 (D.C. Cir. 1987) (rejecting the suggestion "that 'fitness for review' alone is always sufficient to make a claim ripe").[10]

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[10] See also *American Fed'n of Gov't Employees* v. *FLRA*, 750 F.2d 143, 144 (D.C. Cir. 1984); *American Trucking*

It is true that, in a narrow category of cases, the D.C. Circuit has dispensed with the hardship test. This exception to the general rule originated in *Eagle-Picher Indus., Inc.* v. *United States EPA*, 759 F.2d 905 (1985). In that case, Eagle-Picher sought to challenge an EPA regulation adopted pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9601 *et seq.*, but failed to bring the challenge within 90 days of the regulation's promulgation, as an applicable CERCLA provision required. Eagle-Picher argued that the lateness of its challenge should be excused on the ground that, had it filed suit within the 90-day period, the suit would not have been ripe. The D.C. Circuit disagreed. After concluding that the issue would have been fit for judicial resolution within the 90-day period, the court declared that "[w]e need not proceed in this case to the second prong of the *Abbott Laboratories* test," because "[w]here the first prong of the ripeness test is met *and Congress has emphatically declared a preference for immediate review*, * * * no purpose is served by proceeding to the second prong." 759 F.2d at 918 (emphasis added).[11] The *Eagle-Picher* exception

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Ass'ns v. *ICC*, 747 F.2d 787, 790 (D.C. Cir. 1984); *Tennessee Gas Pipeline Co.* v. *FERC*, 736 F.2d 747, 749 (D.C. Cir. 1984); *South Carolina Elec. & Gas Co.* v. *ICC*, 734 F.2d 1541, 1545 (D.C. Cir. 1984); *Alascom, Inc.* v. *FCC*, 727 F.2d 1212, 1217 (D.C. Cir. 1984); *Air New Zealand Ltd.* v. *CAB*, 726 F.2d 832, 838 (D.C. Cir. 1984); *Baltimore Gas & Elec. Co.* v. *ICC*, 672 F.2d 146, 149 (D.C. Cir. 1982).

[11] Accord *National Recycling Coalition, Inc.* v. *Browner*, 984 F.2d 1243, 1249 (D.C. Cir. 1993); *Her Majesty the Queen* v. *United States EPA*, 912 F.2d 1525, 1533 (D.C. Cir. 1990); *National Recycling Coalition, Inc.* v. *Reilly*, 884 F.2d 1431,

plainly does not apply here, since there is nothing in 42 U.S.C. 5908 suggesting that Congress favored immediate challenges to patent right determinations. Petitioners do not contend otherwise.

2. Petitioners also contend (Pet. 15-22) that, assuming they were required to show hardship under the second prong of the *Abbott Laboratories* test, they have done so. That is a fact-specific question that both lower courts have resolved against petitioners. Further review of that factual claim is unwarranted. See, *e.g.*, *Goodman* v. *Lukens Steel Co.*, 482 U.S. 656, 665 (1987); *United States* v. *Doe*, 465 U.S. 605, 614 (1984). In addition, the Federal Circuit, which has exclusive appellate jurisdiction in cases relating to the patent laws, see 28 U.S.C. 1295(a)(1); Pet. App. A7-A8, has particular expertise in the subject matter of this suit. "Because of the unique character of the Federal Circuit," its conclusion in this case that adjudication of petitioners' challenge to the Determination should be withheld pending the outcome of the Interference is "entitled to special deference." *United States* v. *Fausto*, 484 U.S. 439, 464 n.11 (1988) (Stevens, J., dissenting).

3. Petitioners' contention (Pet. 19-21) that their property has been taken without due process is without merit. The district court expressly dismissed petitioners' complaint *without prejudice*. Pet. App. B8. Therefore, they are at complete liberty to refile their complaint at such time as their suit is ripe. It does not deny petitioners due process to postpone review of the Determination pending the outcome of the Interference when there is no evidence of hardship in

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1434 (D.C. Cir. 1989); *Consolidation Coal Co.*, 824 F.2d at 1081.

so doing. Cf. *Thunder Basin Coal Co.* v. *Reich*, 114 S. Ct. 771, 781-782 (1994).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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JUNE 1994

☆ U. S. GOVERNMENT PRINTING OFFICE: 1994 301157 86160

No. 93-1450

(3)

Supreme Court, U.S.
FILED
JUN 13 1994
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OFFICE OE THE CLERK
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Page

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Consolidated Rail Corp. v. United States,
896 F.2d 574 (D.C. Cir. 1990) 2

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& Health Review Comm'n,
824 F.2d 1071 (D.C. Cir. 1987) 2

Eagle-Picher Industries, Inc. v. U.S. EPA,
759 F.2d 905 (D.C. Cir. 1985) 1

No. 93-1450

In The
SUPREME COURT OF THE UNITED STATES
October Term, 1993

CEDARS-SINAI MEDICAL CENTER, WARREN S. GRUNDFEST, M.D., JAMES S. FORRESTER, M.D., and FRANK LITVAK, M.D.,
Petitioners,

vs.

SECRETARY OF THE UNITED STATES DEPARTMENT OF ENERGY
Respondent.

PETITIONERS' REPLY BRIEF

The Secretary of Energy, in arguing that there is no conflict between the circuits as presented in the Petition, misleadingly characterizes the District of Columbia Circuit's holding in *Eagle-Picher Industries, Inc. v. U.S. EPA*, 759 F.2d 905 (D.C. Cir. 1985). This is evident from the following:

The Opposition states:

> [I]n a *narrow* category of cases, the D.C. Circuit has dispensed with the hardship test. . . . The *Eagle-Picher* exception plainly does not apply here, since there is nothing in 42 U.S.C.

> 5908 suggesting that Congress favored immediate challenges to patent right determinations.

(Opposition, pp. 10-11; emphasis added.)

But the District of Columbia Circuit has said:

> The dissent's attempt to characterize *Eagle-Picher* as a "narrow exception" to an absolute rule requiring special hardship in all cases, applicable only where Congress has explicitly indicated a preference for immediate review . . ., finds no support in *Eagle-Picher* itself or other ripeness decisions of this court or in *Abbott Laboratories*, which places no such limit on the court's power to determine when the balance tips in favor of immediate review.

Consolidation Coal Co. v. Federal Mine Safety & Health Review Comm'n, 824 F.2d 1071, 1082 n.12 (D.C. Cir. 1987).

In other words, the District of Columbia Circuit's exception to application of the hardship prong is not narrow; *Consolidated Rail Corp. v. United States*, 896 F.2d 574 (D.C. Cir. 1990), cited in the Petition, means what it says. And what *Consolidated Rail* says conflicts with the Federal Circuit's application of the hardship test to petitioners. Clearly, the District of Columbia and Federal Circuits are in conflict.

The Secretary's attempt, to depict the District of Columbia Circuit's exception to application of the hardship test as narrow, is a transparent attempt to avoid review. But not only does that exception exist, that exception is growing. And the District of Columbia

Circuit's exception conflicts with the Federal Circuit's refusal to recognize such an exception in similar cases. The Petition should be granted so that this conflict may be resolved.

DATED: June 10, 1994.

Respectfully Submitted,

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